UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

MARY MADISON,

Plaintiff,

v.

CREATIVE WERKS, LLC,
and Steve Schroeder, individually,
Defendants

Civil Action No. Case No. 23CV16476
Honorable Judge Manish S. Shah

**PLAINTIFF'S MEMORANDUM FOR SUMMARY JUDGMENT**

**JUDICIAL ADMISSION-ADVERSE EMPLOYMENT ACTION IS UNDISPUTED**

Defendants judicially admitted that Plaintiff is "no longer employed by the Defendant" and that she was suspended on October 26, 2022 (Undisputed Facts #2 & 15). The EEOC Charge Dkt. #1-Exhibit 1 further details that this paid suspension was converted to an unpaid suspension on November 8, 2022, (Mary Madison Declaration, hereinafter "MM Dec." Exhibit 20) *shortly after Plaintiff objected and requested legal counsel (Undisputed Fact #44)*, and that Plaintiff was not paid a $2,500 signing bonus due on October 27, 2022, as confirmed by her offer letter, Dkt. #1-Exhibit 7. (Undisputed Facts 43-46)

Most critically, Defendants' Amended Answer presents a direct contradiction that eliminates any genuine dispute regarding the occurrence of an adverse employment action. While admitting Plaintiff is "no longer employed" and later asserting "termination" as a basis for their affirmative defense, Defendants explicitly *denied* terminating Plaintiff's employment in Paragraph 11(b) of their Amended Answer Dkt. #53. This denial, when juxtaposed with their other admissions and

defenses, constitutes a judicial admission that they did *not* terminate Plaintiff (Undisputed Fact #3), which is further supported by the absence of any termination or adverse performance documentation in Plaintiff's file (Undisputed Fact #61), as also admitted by Defendants (Undisputed Fact #18-20). If Defendants did not terminate Plaintiff, then any stated "legitimate, non-discriminatory reasons" for termination are irrelevant. The Fact remains that Plaintiff suffered multiple adverse employment actions (suspension, non-payment of bonus, conversion to unpaid status, and de Facto termination-(Undisputed Facts 15, 37, 43, &46) without a legitimate, non-discriminatory reason *for termination* being admitted. This contradiction, coupled with the offer of a severance package MM Dec. Exhibit 23, & Jordan T. Hoffman Declaration, hereinafter "JTH Dec."# 6 further solidifies the adverse nature of the employment action.

Therefore, there is no genuine dispute that Plaintiff suffered multiple adverse employment actions, including suspension, non-payment of a bonus, conversion to unpaid status, and de Facto termination (Undisputed Facts 15, 44 & 46)

**PLAINTIFF ESTABLISHES A PRIMA FACIE CASE FOR EACH CLAIM WITH UNDISPUTED FACTS.**

**1. Retaliation (Title VII / § 1981):**

(1) Plaintiff engaged in statutorily protected activity (Undisputed Facts #9, 14, 16, 33, 34 &51); (2) she suffered an adverse employment action (Undisputed Facts #15, 35-37, 39, 40, 46, 55, 57, 58 & 70); and (3) there was a causal link between the two (Undisputed Facts #28, 44, & 45). *See Burlington N. & Santa Fe Ry. Co. v. White*, 548 U.S. 53, 68 (2006).

**Direct Evidence of Retaliation**

Defendants' suspension letter (Oct. 26, 2022) explicitly ties Plaintiff's suspension to her risk analysis and discussions with Defendant Schroeder about the FDA investigation/Audit and operational contraventions (Undisputed Fact 38). This constitutes a direct admission that adverse action was taken because of Plaintiff's protected activity, eliminating the need for inference and satisfying the McDonnell Douglas burden-shifting.

Adverse employment actions followed shortly after Plaintiff's protected activity, satisfy temporal proximity requirements (*Clark County Sch. Dist. v. Breeden*, 532 U.S. 268, 273 (2001)). Within three (3) business days, it is an undisputed Fact that Defendants excluded Plaintiff from meetings, the internal investigation, suspended Plaintiff, altered Plaintiff's suspension status, withheld financial compensation, and falsely portrayed Plaintiff as an alarmist and incompetent, reinforcing retaliatory motive and pretext (Undisputed Facts # 40, 35-38, 43-44, 46, 22 MM Dec. Exhibit 31 & JTH Dec. #11-Exhibit 4 (*Burlington N.*, 548 U.S. at 68).

Undisputed Facts: Defendants denied Plaintiff's race and gender in their Answer (Dkt. #53 pg 5 ¶1). Defendants admitted Plaintiff was hired as Quality Regulatory Manager for her expertise, with no termination or adverse performance records (Undisputed Facts #18-20). Defendants admitted that it suspended Plaintiff, and the suspension letter eliminates any legitimate (Undisputed Fact #38), non-retaliatory justification, reinforcing Plaintiff's entitlement to summary judgment on retaliation claims. Courts recognize that a plaintiff may establish pretext by showing both a prima facie case and sufficient evidence to discredit the employer's stated reason (Reeves, 530 U.S. at 133). Here, both elements are met. In Title VII retaliation claims, once causation is established under the but-for standard (Nassar, 570 U.S. at 338), liability is triggered. Defendants admitted Plaintiff's comparator was not disciplined, confirming disparate

treatment (Undisputed Facts # 49, 50, 52 & 53) (*McDonnell Douglas*, 411 U.S. at 802); (Saint Francis College v. Al-Khazraji, 481 U.S. 604 (1987)). No documented performance deficiencies exist in Plaintiff's personnel file (Undisputed Facts # 18-20, MM Dec. Exhibits 20 & 22 & JTH Dec. #9), reinforcing pretext (*Burdine*, 450 U.S. at 255-56). Defendants failed to provide a legitimate, non-discriminatory reason for Plaintiff's suspension, reinforcing pretext.

Defendants' blanket denials contradict the record and fail to create a genuine dispute under Rule 8(b), reflecting improper pleading. Courts reject conclusory denials lacking factual support (Iqbal, 556 U.S. at 662; *Twombly*, 550 U.S. at 544), and without admissible evidence to rebut Plaintiff's assertions, summary judgment is appropriate (*Celotex*, 477 U.S. at 317; *Anderson*, 477 U.S. at 242). Defendants' refusal to acknowledge basic Facts reinforces pretext, procedural irregularities, and bad faith, further validating Plaintiff's claims (Undisputed Facts # 1, 27, 68 & 69)

**2. Plaintiff Was Subjected to a Hostile Work Environment**

Defendants admit they were notified of the Plaintiff's disparate treatment (Undisputed Fact #16), but failed to investigate (Undisputed Fact #28) or take corrective action.

The undisputed Facts in this case demonstrate a severe and pervasive pattern of retaliatory and discriminatory harassment, establishing Defendants' liability under Title VII. This pattern includes Defendants' actions such as unfair scrutiny and suspension for Plaintiff's FDA compliance duties, combined with false allegations of misconduct (Undisputed Fact #29) and the fabrication of a pretextual investigation (Undisputed Facts 27, 40 & 68). Furthermore, Defendants unlawfully withheld Plaintiff's earned bonus (Undisputed Fact 46) and made repeated misrepresentations to government agencies (Undisputed Facts 65-67). Defendants'

conduct—including the exclusion of Plaintiff from key meetings, imposition of disparate workplace conditions, and targeted interference with her future employment through a subpoena to the CEO of her subsequent employer—fostered an environment of intimidation, isolation, and unequal treatment (Undisputed Facts ¶¶ 49–55 & 70). These actions collectively altered the terms and conditions of Plaintiff's employment and created a workplace that was objectively and subjectively hostile, satisfying the "severe or pervasive" standard under Harris v. Forklift Sys., Inc., 510 U.S. 17, 21 (1993), and Meritor Sav. Bank v. Vinson, 477 U.S. 57, 67 (1986).

Moreover, Defendants' failure to investigate Plaintiff's complaints of disparate harassment (Undisputed Fact # 28), strengthens Title VII liability (Faragher v. City of Boca Raton, 524 U.S. at 775), and the adverse nature of these actions, including pay changes and false statements to IDHR(Undisputed Facts # 31, 46 & 65-67), directly confirms the causal link to Plaintiff's protected activity (Nassar, 570 U.S. at 338).

**3. Disparate Treatment Analysis Supports Plaintiff's Claims**

Erich Zicher, a white male comparator, oversaw adulterated product entering into the stream of commerce (Undisputed Facts # 52-53), in violation of the FFDCA, confirmed by two FDA consumer complaints, an FDA investigation, and an audit on September 28-29, 2022 (Undisputed Facts # 9, 10 & 12). The FDA inspector issued Zicher an FDA Form 482, as the person most in charge, and critiqued Zicher's work product in response to a request for information. Despite being the person most in charge, Zicher provided the wrong document in response to the request, and the FDA inspector noted that it was hard to read, not easy to understand, and contained errors (Undisputed Facts # 52). Yet, despite clear regulatory failures, Defendants took no adverse action against Zicher (Undisputed Facts # 49-51, 53), while Plaintiff

was swiftly suspended, subjected to a myriad of adverse employment actions and de Facto termination (Undisputed Facts # 15, 35-37, 39-40, 46, 55, 57, 58 & 70) —without investigation or due process (Undisputed Fact # 40).

Additionally, Nestlé audits repeatedly cited non-conformances year after year (MM Dec. Exhibit 10). Despite these documented failures, Defendants admitted Zicher faced no discipline or adverse action—including for adulterated product entering the stream of commerce or the repeated non-conformances in annual Nestlé audits (Undisputed Facts # 10, 12, 49, 50, 52 & 53-MM Dec. Exhibit 10), while Plaintiff was penalized for raising compliance concerns and analogous issues (Coleman v. Donahoe, 667 F.3d 835, 849 (7th Cir. 2012). This evidence, along with the ongoing pattern of unchecked violations, highlights disparate treatment and pretext, supporting Plaintiff's claims and permits a jury to conclude that Plaintiff's race and sex caused the adverse action. (*Abrego v. Wilkie*, No. 17-3413 (7th Cir. 10/30/2018)).

**4. Conspiracy to Deprive Plaintiff of Equal Protection**

Defendants—Creative Werks, LLC, Steve Schroeder, and their counsel—engaged in a coordinated conspiracy to deprive Plaintiff of equal protection and retaliate against her. This conspiracy is evidenced by overt acts including: a sham "independent investigation" designed to fabricate false justifications (Undisputed Facts # 27, 68 & 69); concealment of evidence through denying Plaintiff access to her personnel file (Undisputed Facts 20, 61 JTH Dec. # 9 & MM Dec. Exhibits 20 & 22) and invoking privilege over investigation results (Undisputed Fact # 68); false statements to government agencies regarding Plaintiff's performance and adverse actions (Undisputed Facts #65-67); withholding Plaintiff's earned sign-on bonus under baseless pretenses (Undisputed Fact #46); and persistent litigation misconduct, such as unauthorized

filings, false statements to the Court, and attorney threats and directing a subponea to the CEO of Plaintiff's subsequent employer (Undisputed Fact #70). These actions directly injured Plaintiff through her suspension, transition to unpaid status, bonus withholding, termination, and reputational harm.

**V. Evidence of Pretext and Disparate Treatment (Title VII) is Undisputed**

1. Temporal Proximity and Lack of Pre-Suspension Investigation: Defendants suspended Plaintiff on October 26, 2022—just five days after she discussed compliance failures with Mr. Schroeder —without conducting a pre-suspension investigation (Undisputed Facts # 15, 33, 36, 39-40). This close temporal proximity and lack of investigation strongly indicate retaliation rather than legitimate discipline, meeting the temporal proximity standard for retaliation claims (*Clark County Sch. Dist. v. Breeden*, 532 U.S. 268, 273 (2001)).

2. Legally Barred and Inconsistent Justifications for Termination: Defendants have provided inconsistent reasons for Plaintiff's separation. While their Amended Answer implies her suspension was due to "unfounded allegations" related to her conversation with Mr. Schroeder (Dkt. #53, ¶76), this assertion is inherently unreasonable given Defendants' admission that Plaintiff "did not participate in any investigation prior to being informed of her suspension." (Undisputed Facts # 39-40). Hence, Defendants could not reasonably know that the allegations were unfounded. Defendants appear to have relied solely on the word of Erich Zicher, who, Defendants characterize him as part of its operation relating to regulatory compliance and quality activities (Undisputed Fact #48), who was responsible for ensuring compliance and whose conduct during the FDA inspection involved providing an incorrect and hard-to-read document, and who oversaw adulterated product entering the stream of commerce (Undisputed Fact # 52), as confirmed by FDA consumer complaints and investigation

(Undisputed Fact # 10). This uninvestigated reliance on a potentially culpable individual's word, without affording Plaintiff due process, is indicative of a predetermined outcome and is similar to issues of pretext and uninvestigated claims seen in cases like *Humphries v. CBOCS West, Inc.*, 474 F.3d 387, 407 (7th Cir. 2007) They later informed the DOL and IDHR that Plaintiff was terminated for "incompetency"(Undisputed Facts # 65-66). This shifting and inconsistent justification is classic evidence of pretext. (*Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133 (2000)).

Crucially, Defendants admitted that they provided Plaintiff's personnel file and "nothing was withheld from it"(Undisputed Fact #61). The Illinois Personnel Record Review Act (IPRRA) explicitly prohibits employers from using information not contained in an employee's personnel record against the employee in a judicial or administrative hearing. Therefore, Defendants are legally barred from asserting "termination or poor performance or incompetency" as a reason for any adverse actions taken, as it is not documented in her personnel file (Undisputed Facts # 60-61). Thus rendering their defense legally insufficient and further demonstrating pretext as a matter of law.

Even if Defendants assert a legitimate, non-discriminatory reason for Plaintiff’s termination, undisputed facts prove it is mere pretext, which the Seventh Circuit defines as "unworthy of credence" or a "lie" (Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 143 (2000)). Defendants' decision-making process is fundamentally flawed and indicative of pretext, as demonstrated by their December 20, 2022, "independent investigation" and subsequent concealment of key documentation (Undisputed Facts # 68-69). Plaintiff explicitly warned Defendants on November 1 and November 8, 2022, that any investigation would be a “pretext and a farce” and a “subsequent remedial measure” (MM Dec. Exhibit 20), proving her

recognition of their disingenuous motives before the meeting even occurred. Indeed, the December 20, 2022, meeting itself focused on Plaintiff's background and alleged "after-acquired evidence" rather than her suspension's stated reason, confirming its design to retroactively justify a predetermined adverse action (Undisputed Fact 68). Plaintiff and her counsel directly confronted Defendants during this meeting, unequivocally labeling it a "pretext and a farce" (JTH Dec. #4 & MM Dec. pg. 14 ¶7).

Further evidencing pretext and bad faith is Defendants' application of privilege—and shifting their stance on the reason for Plaintiff's termination in the DOL and IDHR matter and in this litigation—signaling an attempt to conceal unfavorable evidence (Undisputed Facts 29 & 65-68). Defendants' refusal, especially if the investigation was purportedly to determine the validity of Plaintiff's "unfounded allegations," suggests an attempt to conceal information that undermines their defense. Additionally, their use of undocumented assertions in judicial proceedings violates the Illinois Personnel Record Review Act (IPRRA) (Undisputed Facts # 20 & 61). This pattern of concealment supports an adverse inference that the withheld records would further expose discriminatory and retaliatory motives. *Trask-Morton v. Motel 6*, 534 F.3d 672, 681 (7th Cir. 2008); *Chambers v. NASCO*, 501 U.S. 32, 46 (1991)

Undisputed Facts: Defendants suppressed Plaintiff's personnel file, misused legal counsel, and invoked privilege to withhold investigative findings (*Jones v. City of Chicago, 856 F.2d 985, 992-93 (7th Cir. 1988)*; *Upjohn*, 449 U.S. at 383). Coordinated legal tactics to obscure retaliatory motives demonstrate conspiracy (*Griffin*, 403 U.S. at 88). Misuse of expert testimony to justify adverse actions reinforces pretext and manipulation (*Reeves*, 530 U.S. at 133). Unpaid suspension, false statements to IDHR, and procedural manipulation confirm retaliation (Undisputed Facts # 43 & 65-68) (*Nassar*, 570 U.S. at 338). Defendants' efforts to isolate

Plaintiff (Undisputed Facts # 40 & 55), undermine credibility (Undisputed Facts # 22, 58, 65-67), and impose disparate treatment support hostile work environment claims (Undisputed Facts # 49, 50, 52-55 & 57-58) (*Harris*, 510 U.S. at 17). Race-based discrimination and conspiracy to obstruct legal protections violate § 1981 and § 1985(3) (*CBOCS West*, 553 U.S. at 442; *Griffin*, 403 U.S. at 88).

**VI. Basis for 42 U.S.C. §§ 1981 and 1985(3) Claims.**

Plaintiff's claims under 42 U.S.C. § 1981 (racial discrimination in contracting/employment) and § 1985(3) (conspiracy to deprive civil rights) are also supported by the undisputed Facts. The discriminatory animus and disparate treatment, particularly concerning Mr. Zicher's unpunished conduct (Undisputed Facts # 49-50 & 52-54), versus Plaintiff's suspension for raising compliance issues, establish the "but-for" causation required for § 1981.

For § 1985(3), the undisputed overt acts demonstrate the existence of a conspiracy and acts in furtherance thereof. Defendants—Creative Werks, LLC, Steve Schroeder, and their counsel—engaged in a coordinated effort evidenced by:

- Defendants engaged in a sham 'independent investigation' designed to fabricate false justifications for Plaintiff’s suspension and termination. This required a meeting of the minds, where Defendants collectively orchestrated Plaintiff’s forced consultation with outside counsel (Undisputed Fact # 69), excluded her from their internal investigation (Undisputed Fact # 40), and strategically retained an 'expert witness'—not qualified in the relevant field—to impugn her character and professional standing (Undisputed Facts # 63 & 58). Such concerted efforts strongly indicate deliberate collusion, reinforcing Plaintiff’s conspiracy claim

- Concealing evidence by denying Plaintiff access to her personnel file (Undisputed Facts # 18-20, & 59-61) and invoking privilege over investigation results (Undisputed Facts # 62 & 68)
- Making false statements to government agencies (DOL and IDHR) regarding Plaintiff's performance and the reasons for her adverse actions (Undisputed Facts # 65-67).
- Plaintiff's sign-on bonus was due the day after her suspension, yet Defendants offered an illogical justification for withholding it— Defendants admitted withholding the bonus "based on the date of her suspension and termination" (Undisputed Fact # 45). **The Contradiction:** For the "termination date" to be a valid reason for withholding a bonus due on October 27, 2022, Plaintiff would logically have had to be terminated *before* that date, despite the bonus letter implying repayment only if leaving before a year (Dkt. #1-Exhibit 7). This evidenced Defendants' concerted efforts to manufacture justifications, further exposing pretext.
- Engaging in a pattern of litigation misconduct, including unauthorized filings, misrepresentations to the Court, and attorney intimidation tactics—such as issuing a subpoena to the CEO of Plaintiff's subsequent employer, probing into performance expectations and any complaints lodged against Plaintiff's supervisor.

These admitted and undisputed overt acts, when viewed together, establish the "existence of a conspiracy" and "an act furthering the conspiracy" elements of a § 1985(3) claim.

## VII. DEFENDANTS' FAILURE TO CONTEST KEY CLAIMS CONFIRMS LIABILITY.

### Defendants' Answer is Procedurally Deficient Under Rule 8(b)

A. Failure to Properly Deny Under Rule 8(b)(2)- Rule 8(b)(2) requires Defendants to fairly respond to the substance of each allegation in the Complaint.

Instead of directly addressing the allegations regarding intentional discrimination, conspiracy, harassment, and retaliation, Defendants attempt to evade responsibility by dismissing them as mere legal conclusions and general denials. Paragraphs 18-20, 22, 28-29, 49…. 78, 84, 94, 104, 107, 108, 109 etc… contain Factual allegations (e.g., Paragraph 104- hiring an expert witness for discriminatory purposes, using legal counsel to facilitate and in furtherance of a scheme, etc.), Courts have ruled that mixed allegations of Fact and law still require a substantive response (*Ashcroft v. Iqbal, 556 U.S. 662 (2009); Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007)*).

Defendants' remaining answers to Plaintiff's complaint were general denials that failed to fairly respond to the substance of each allegation, without pointing to or specifically refuting key Factual allegations; those allegations are deemed admitted under Rule 8(b)(6).

For Example:

Defendants' general denials of Plaintiff's Title VII (race and sex), § 1981, § 1985, harassment, retaliation, and de Facto termination claims in Paragraphs 8, 11 & 12 (Dkt. 53, pgs. 2-3)—as well as their hostile work environment denial (Paragraph 73)—raise procedural concerns under Rule 8(b), Fed. R. Civ. P.

Courts disfavor blanket denials, especially when they fail to specify Factual disputes or contradict objective evidence (*Twombly*, 550 U.S. 544 (2007); *Celotex*, 477 U.S. 317 (1986)). Defendants outright denied Plaintiff's race and sex (Undisputed Fact # 1), contradicting basic Factual reality and failing to address undisputed material Facts related to Plaintiff's employment, suspension, and treatment. Defendants simultaneously asserted an after-acquired evidence defense, directly contradicting their prior denial of Plaintiff's termination (Undisputed Fact #3), reinforcing procedural inconsistencies and bad faith litigation tactics. Defendants waived

additional defenses by failing to raise them in their Rule 12 motion (Dkt. # 19), which was denied (Dkt. #38). Under Rule 12(h)(1), Fed. R. Civ. P., defenses not timely raised are waived, preventing later assertion. This failure to acknowledge key Facts strengthens Plaintiff's claims of pretext, retaliation, and hostile work environment, particularly when considered alongside Defendants' procedural inconsistencies, adverse actions, and waived defenses (*Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133 (2000)).

**B. Blanket Denial Violates Rule 8(b)(3)**

Rule 8(b)(3) permits general denials only when a defendant, in good faith, intends to deny every allegation. Here, Defendants did not deny all allegations and instead used conditional denials, such as: "To the extent a response is required, Defendants deny the same" (Undisputed Fact # 4). Such conditional denials are insufficient under federal pleading standards State Farm Mut. Auto. Ins. Co. v. Riley, *199 F.R.D. 276* (N.D. Ill. 2001) because they fail to clarify which allegations are actually disputed. Defendants' vague phrasing obscures what is being denied, preventing Plaintiff from determining which Facts remain undisputed.

**C. Defendants' Response Should Be Treated as an Admission Under Rule 8(b)(6)**

Defendants' failure to properly deny key Factual assertions—such as the premeditated and malicious nature of their conduct, misuse of counsel and expert testimony as discriminatory tactics, and their gaslighting and humiliation of Plaintiff in paragraphs 82, 83, 98, 104, 109 of Dkt. #53 and others (Undisputed Facts # 4 & 5), —triggers Rule 8(b)(6), Fed. R. Civ. P., which states that an allegation is admitted if not effectively denied (Keene Corp. v. Int'l Fidelity Ins. Co., *561 F.3d 596, 600 (7th Cir. 2009)).*

**D. Affirmative Defenses-Dkt. #53 – Burden of Proof Issues**

Rule 8(c) requires affirmative defenses to provide sufficient Factual basis, ensuring Plaintiff is properly notified of the defense strategy. Courts reject vague or conclusory defenses (*Twombly*, 550 U.S. 544 (2007); *Iqbal*, 556 U.S. 662 (2009)).

Defendants assert five bare-bones affirmative defenses, all procedurally defective and unsupported by specific Facts or evidence:

Same Actor Inference and Mixed Motive (First & Fourth Defenses) fail to rebut pretext or retaliation and are not recognized under Rule 8(c). The First Defense is not legally cognizable and appears intended to prejudice Plaintiff rather than assert a valid defense—making it impertinent and subject to striking under Rule 12(f), Fed. R. Civ. P.

After-Acquired Evidence (Second Defense): Fails Rule 8(c) and the *McKennon standard (513 U.S. 352 (1995))*, which requires admissible evidence discovered after termination. Defendants knew of the alleged evidence in December 2022, contradicting their defense and triggering judicial estoppel. Further, Defendants have not to date indicated a formal termination date pursuant to the IPRA; hence, this defense must be stricken under Rule 12(f).

Same Decision (Third Defense): Fails Rule 8(c) & Rule 12(f), relying on post-hoc justifications unsupported by contemporaneous records, violating procedural and substantive legal standards (*Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133 (2000)).

Failure (Fifth Defense): Re-litigates dismissed arguments and contradicts the Court's prior ruling (Dkt. # 38), making it redundant, legally irrelevant, and ripe for striking under Rule 12(f) *Heller*

*Fin., Inc. v. Midwhey Powder Co.*, 883 F.2d 1286, 1294 (7th Cir. 1989); *Convergent Techs., Inc. v. Mid-Am. Nat. Bank of Chi.*, 915 F.2d 1111, 1114 (7th Cir. 1990).

Plaintiff has concurrently filed a Rule 12(f) motion to strike these procedurally and evidentiary deficient defenses, preserving all objections without waiving any right to future challenges.

**VIII. Waiver of Claims**

Defendants waived their right to challenge Plaintiff's retaliation, hostile work environment, § 1981, and § 1985 claims by failing to raise them in their Rule 12 Motion (Dkt. #19), as confirmed by the Court's ruling (Dkt. #38). Under Rule 12(h)(2) and *Beaumont v. GM*, 102 F.3d 302, 307 (1996), unraised defenses are barred. With no genuine disputes of material fact, summary judgment is proper under Rule 56.

**Law of the Case & Waiver**

The Court has already upheld Plaintiff's retaliation, hostile work environment, §§ 1981 and 1985 claims, confirming they were properly pleaded. Under the law of the case doctrine (*Arizona v. California*, 460 U.S. 605, 618 (1983)), Defendants cannot revive dismissed arguments or raise new defenses. The Court should enforce its ruling and grant summary judgment.

**CONCLUSION**

Because Defendants' judicial admissions eliminate factual disputes, comparator evidence proves pretext, financial harm confirms retaliation, missing records warrant adverse inference, procedural failures invalidate their defenses, and abuse of privilege reinforces misconduct, Plaintiff respectfully requests that this Honorable Court enter summary judgment in her favor under Rule 56.

Dated: June 24, 2025 Submitted By: /S/
Mary Madison

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

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| MARY MADISON,<br><br>Plaintiff<br>V.<br><br>Creative Werks, LLC<br>a Delaware Limited Liability Company<br><br>Defendant. | ) | No. 23CV16476<br>Honorable Judge Manish S. Shah |

**DECLARATION OF MARY MADISON**

Mary Madison, for her declaration, pursuant to 28 U.S.C. §1746, states as follows:

I am over twenty-one years of age and am competent to testify to the matters set forth in this Declaration. The facts stated herein are within my personal knowledge and are true and correct. I was offered a job as the Quality Regulatory Manager at Creative Werks Elk Grove facility on September 20, 2022. My compensation was 95,000.00 dollars per year, plus 10% bonus and a sign on bonus of $2,500.00. See Exhibit 1

The job description referenced in Creative Werks rebuttal to my complaint is for a Regulatory Specialist and therefore is not applicable to me. See Respondent's Exhibit1

I began working on September 27, 2022 at Creative Werks as the Quality Regulatory Manager.

The responsibilities entailed compliance with the Food Safety Modernization Act "hereinafter referred to as FSMA[1]" and other regulatory schemes such as the Bioterrorism Act of 2002 (Food Defense) in addition to being a liaison between customers and the company regarding compliance quality, regulatory and customer requirements (See Exhibit 2 FDA report pg. 8)

[1] FSMA amended the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

On September 27, 2022, I was instructed to report to Creative Werks' Bartlett facility on September 28, 2022 because the FDA was coming to the facility.

**DAY ONE OF THE FDA VISIT CONSUMER COMPLAINT REVIEW**

After reporting to the facility on September 28, 2022 and while waiting for the FDA inspector Erich Zicher began making disparaging and belittling remarks about the FDA inspector; including but not limited to her effectiveness and abilities as an FDA inspector. Mr. Zicher's remarks along the lines of "she is stupid, she does not know anything etc. He further demeaned her for referencing inadequacies that made it seem that he was incompetent or stupid in the report that she had previously written in July of 2022 relative to the Elk Grove facility. He spent a significant amount of time complaining about her and disparaging her.

Mr. Zicher also spoke at length about his past history as a golf pro and being a music major.

Upon the inspector's arrival at approximately 2:12 pm, she stated that she was there in reference to a customer complaint. She remarked that she was able to gain access into the facility without being properly vetted (See Exhibit 2 pg. 16 § Food Defense) Moreover, the inspector stated that the facility had not been inspected previously because it was not properly registered with the FDA.

The attendees on behalf of Creative Werks were Mr. Erich Zicher, Ms. Angela Knabe, Anupam Sharma and myself. We introduced ourselves to the inspector. Mr. Zicher identified himself as the person most in charge. Subsequently, the inspector issued a notice of inspection--FDA form 482 to Mr. Zicher. We were instructed by the FDA inspector to provide any evidence of being a Preventive Control Qualified Individual, ("hereinafter PCQI"). Mr. Zicher, Ms. Knabe and I provided that information to the inspector.

The inspector began to conduct her interview indicating that there was a consumer complaint made in October of 2021 regarding a Cheetos product that she wanted to discuss (See Exhibit 3). In response, Mr. Zicher refused to produce documents relative to the complaint without permission from the client (See Exhibit 2 pg. 15 § Refusal). He further indicated that he was not aware of a complaint in October of 2021, but was aware of a complaint in May in 2021 regarding a Pepsi Cheeto product (See Exhibit 4 pg. 4). Mr. Zicher indicated that they were aware of a non-conformity relative to burnt seals. He also indicated that they had conducted an investigation, but further indicated that this was no longer an issue, as Creative Werks was no longer doing business with Pepsi (See Exhibit 2 pg. 4 ¶5). There was a somewhat heated discussion between Mr. Zicher and the inspector regarding the timing and length of the investigation.

During the relevant time, Mr. Zicher did not offer any tangible evidence or any particulars on the investigation or any subsequent remedial measures taken to mitigate the non-conformance and to prohibit adulterated food from entering the stream of commerce.

The inspector left at approximately 4:30 pm and indicated that she would return on the next day, Thursday, September 29, 2022.

Mr. Zicher continued to disparage the FDA inspector's competency. He also stated that the production and tendering of documents is not permitted and if we have to produce documents, we are only to show them electronically.

**DAY TWO OF THE FDA VISIT SITE INSPECTION**

The FDA inspector returned on Thursday, September 29, 2022 at approximately 1:00 pm. The inspector reviewed the consumer complaint from the previous day continuing to make inquiries about the timing and resolution of the complaint. Mr. Zicher again denied having any knowledge of the October 2021 complaint.

The inspector moved on and began doing an audit inspection of the company's records and relevant practices. Mr. Zicher was not initially compliant with the request; refusing to produce the requested information, but ultimately acquiesced.

The inspector asked about training. Various types of training were identified, including 5S training. The inspector asked what that was and no one could speak to what that was including Mr. Zicher.

The inspector indicated that she wanted to tour the facility. Of course, I wanted to accompany them because I was new and I wanted to see the facility. Mr. Zicher stated that if I was accompanying them on the facility tour my jewelry needed to be removed. He indicated to me that I had a dress on. However, Ms. Knabe stated that I was all right to go, indicating that the company policy stated that one's extremities were to be covered. There was no exposed flesh; my arms and legs were fully covered.

To minimize the discussion, I informed him that I had pants in the car and that I would change.

I was unable to remove one of my screwed-in stud earrings. Per the FDA, jewelry is permissible if it is secured. Further the rule is geared towards those that come in direct contact with food, food-contact surfaces, and food-packaging materials (See 21 CFR Subpart B § 117.10 (b)(4)). By Mr. Zicher's own admission in his declaration, I could not get the earring out. Moreover, he neglected to state that head covers were used that also covered the ears that could have caught

and restrained any particulate from being introduced in the manufacturing facility; therefore, controlling and minimizing any risk.

I did not pose any safety risk, as I was not going to be working on a line or coming into direct contact with any product, surface or packaging material. Thus, it would have been highly unlikely or improbable that any contamination would have occurred.

I contend that any embellishments from my prescription eyeglasses would not have posed a risk for the same reasons.[2] Additionally, the use of goggles could restrain any particulate from being introduced into the manufacturing facility.

I do not paint my fingernails. Mr. Zicher's statement that my nails were painted is patently false.

Further, I contend that my presence during the inspection was not essential, as I had just started and had not been to the facility before. I had no knowledge about the facility and its operation. Additionally, the person that I was replacing, Ms. Knabe did not accompany them either nor was she invited or required to go on the tour.

Ms. Knabe and I remained in the conference room further suggesting that it was not as crucial as Mr. Zicher is now attempting to make the issue to be.

Upon their return from the tour, it was revealed that the FDA inspector had observed improper sanitation being performed.

Another issue arose when the inspector wanted to take sample labels off the line that was running. Initially Mr. Zicher refused and told the inspector that those labels did not belong to Creative Werks, but their customer, Hersey. Mr. Zicher also indicated that they needed permission from the customer to do so.

Ms. Knabe reached out to Teddy Cadet, the Senior QRC Specialist, from Hersey asking for permission to provide the FDA the labels. Mr. Cadet indicated that it was ok to give them the labels, as they were entitled to these materials during an inspection (See Exhibit 5).

There were five (5) observational findings identified by the FDA inspector at the closing meeting on September 29, 2022. These findings ranged from improper record keeping to sanitation and pest control issues.

[2] Further, even knowing that an inspection was going to take place, there is nothing that could have been done to replace my eyeglasses on such short notice.

The other attendees were perplexed that the inspector raised an issue about the records not being properly kept. Specifically, the records were not dated. No one seemed to know or understand the relevance or importance of the issue raised.

Subsequently, that evening, Mr. Cadet followed up asking what was the reason for the FDA visit.

In response, Mr. Zicher sent out an email entitled "FDA Inspection Routine Inspection" at 9:38 pm on Thursday, September 29, 2022. In it, Mr. Zicher discussed the Pepsi consumer complaint along with identifying the five (5) observations made by the FDA Inspector (See Exhibit 4).

In sum, on September 28 and 29, 2022, I engaged in protected activity[3] when I participated in a FDA audit/inspection that resulted from a consumer complaint at Creative Werks Bartlett facility.

**FOLLOW UP AFTER AND DEBRIEF OF THE FDA VISIT**

On Friday, September 30, 2022, Mr. Zicher solicited input from myself, Ms. Knabe and others on how to couch the FDA visit to craft his response and inform other clients of the FDA visit.

On September 30, 2022, I began performing a Root Cause Analysis of the deficiencies identified in the closing meeting with the FDA.

In performing the Root Cause Analysis of the findings, I observed that there were a number of issues of non-compliance with FSMA and the Bioterrorism Act of 2002.

I engaged in protected activity when I spoke with Mr. Steve Schroeder on Friday, September 30, 2022 regarding the FDA inspection while at the espresso machine. He asked me about the inspection and in particular about what happened with the Pepsi complaint. I indicated that it was an issue relative to the timing of the complaints and investigation. I also indicated that the requests from the FDA inspector were not unreasonable and that documents were not produced to the FDA as requested. Mr. Schroeder stated that he "wanted to change the culture to be more transparent." He also stated that "he hoped that I could be of help to the company."

I further indicated that I was in the process of drafting correspondence to help clarify the requests and findings of the FDA inspector during the visit. Mr. Schroeder told me that he had sent some questions to Mr. Zicher regarding the FDA visit and he asked me to ask Mr. Zicher to share the questions that he sent him with me so that I could respond to them.

As promised, later that afternoon, on Friday, September 30, 2022, I presented for review the corresponding rules, regulations and statutes that underscored the requests and observations

[3] As defined by 21 U.S.C. § 399d (a)(1)

made by the FDA inspector to identify and shore up any outstanding gaps for compliance (See Exhibit 4 pg. 1).

During the relevant time, I had no idea that a number of documents requested did not exist. Nor did I understand that documents that did exist did not meet the requirements of 21 CFR 117 and the food defense under the Bioterrorism Act of 2002.

**REMEDIATION OF OUTSTANDING NESTLÉ AUDIT DEFICIENCIES**

In attempting to remediate outstanding customer audit findings from July of 2022, I discovered that the food safety plans were either inadequate or did not exist in contravention of 21 CFR 117 and other food defense requirements under the Bioterrorism Act of 2002. Additionally, I also discovered that Creative Works had repeated non-conforming audit findings that still had not been mitigated or remediated.

For example, it is a documented fact that Creative Werks only had four (4) food safety plans. Plans that were based on Hazard Analysis Critical Control Points, "hereinafter HACCP[4]." This is contravention of 21 CFR 117.126. Further, none of the required plans were developed for Nestlé.

HACCP is the internationally recognized standard that was the forerunner and the precursor to Hazard Analysis and Preventive Control, "hereinafter HARPC." HARPC became the standard in the United States when the Preventive Control for Human Food, "hereinafter PCHF" rule became final in September 2015. PCHF rule requires food facilities to have a food safety plan in place that includes an analysis of hazards and risk-based preventive controls to minimize or prevent the identified hazards. (FDA https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food)

HARPC-The Preventive control systems emphasize prevention of hazards before they occur rather than their detection after they occur. [5]

Creative Werks is a registered facility under the Bioterrorism Act of 2002, which subjects Creative Werks to the FDA's PCHF rule.

In reviewing Creative Werks records during that relevant period there was no evidence that Creative Werks had ever had PCHF compliance using the HARPC standard.

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[4] The FDA defines HACCP as a "management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product" (FDA 02/25/2022).

[5] Sherod, Anne (11 May 2015). "The ABCs Of Building A Food Safety Plan: From HACCP To HARPC". *foodonline.com*. Archived from the original on 14 December 2018. Retrieved 2 August 2023.

The FDA clearly states that: “This hazard analysis must be written, regardless of whether any hazards requiring a preventive control are identified.” (FDA-Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry § 1.2 2).

The FDA Guidance documents represent the “FDA's current thinking on a topic or FDA’s interpretation of our policy on a regulatory issue” (FDA 2023).

Further, a plan is required even if it is the same product being run at a different facility See 21 CFR 117; Also, see FDA Frequently asked questions on PCHF. https://www.fda.gov/food/food-safety-modernization-act-fsma/frequently-asked-questions-fsma

I communicated to Mr. Zicher these deficiencies and our non-compliance that underscored the audit deficiencies. I was told by Mr. Zicher on several occasions that Donna Bjurlin, from Nestlé, was being picky and that he was not inclined to make any changes (See Exhibit 6). I was also instructed by Mr. Zicher not to reference the regulations and standards when corresponding with Donna on behalf of Nestlé.

**MEDFAST POTENTIAL NEW CUSTOMER-BENSENVILLE**

On October 3, 2022, I met Mr. Zicher at yet another Creative Werks facility in Bensenville to meet with a potential new customer Medfast.

While we were waiting for the potential clients, Mr. Zicher and I discussed the FDA audit/inspection. We discussed the complaint. We also discussed how it seemed that Creative Werks was unaware that it had non-conforming/adulterated product that it should have been aware of since May of 2021 and did nothing to prevent it from entering into the stream of commerce for human consumption. I shared with him that a good starting point was to understand what standards we needed to comply with based upon our operations. I also shared with Mr. Zicher that Mr. Schroeder wanted him to share with me the questions that Mr. Schroeder had sent to him regarding the FDA visit on September 28-29, 2022.

Mr. Zicher indicated that I did not understand the culture there and that he would not be providing me with the information Mr. Schroeder asked me to ask him to share with me. He also indicated that he and Ron Sammeth, the COO, decided what Mr. Schroeder should see and know.

Later during the Medfast visit, several questions were raised by them relative to basic requisites under FSMA relative to likelihood/severity of occurrences for hazards related to their product. For example, the issue arose as to whether Creative Werks performed environmental monitoring. The question was posed after Medfast representatives saw the storage of large amounts of

corrugated boxes in the warehouse. The warehouse presented conditions that supported optimal growth for mold and other microbes. This is a reasonable and foreseeable hazard that could have been easily identified and managed from the proper execution of a science risk based hazard analysis.

**BLUE DIAMOND GROWERS AUDIT-BENSENVILLE**

On the next day, October 4, 2022, I began preparing for an upcoming audit that I was tasked to facilitate on October 6, 2022 on behalf of Blue Diamond Growers "hereinafter BDG." BDG had sent over an audit plan of specific items that they wanted to review during the audit (See Exhibit 7).

In my preparation for the BDG audit, I found a number of deficiencies and in an attempt to remediate them prior to the audit, I informed Mr. Zicher of these deficiencies (See Exhibit 8).

I was told by Mr. Zicher not to worry about the deficiencies because in his experience "no one reads the documents" and to "use whatever documents we have."

I was instructed by Eric Zicher, Director of Food Safety to provide false, inaccurate and misleading information to clients after I specifically pointed out deficiencies in the documentation.

On October 6, 2022, the auditor, Keira Kaur Dhillon came to perform the audit. We began our introductions; Ms. Dhillon went first indicating that one of her previous employers was Kraft Foods. I went next and Mr. Zicher went last. Mr. Zicher told Ms. Dhillon that they had something in common because they both had worked at Kraft. She in turn asked him who was the CEO when he worked at Kraft? Mr. Zicher did not and could not answer her question--The room was filled with silence.

Seemingly to deflect the awkward situation, Mr. Zicher made remarks poking fun at me to Ms. Dhillon that I had all these tabs open on my computer relative to the documents that they had requested to review.

I responded to the effect that since they were kind enough to send over a comprehensive list of what they wanted to review during the audit and in the interest of everyone's time, it seemed prudent to be prepared and not to have to search for documents (See Exhibit 7).

The auditor remarked that the audit exhibited readiness because of the readily available documents (See Exhibit 9).

Unfortunately, there was an issue identified by the auditor in one of the documents she reviewed that could have been identified and remediated. This was not the case because I was instructed to ignore the deficiencies identified (See Exhibit 8).

**FOLLOWING UP ON UNREMEDIATED OUTSTANDING NESTLÉ AUDIT ISSUES**

In an effort to follow up on the outstanding audit non-compliances relative to Nestlé that had been due and owing since July of 2022, I again broached the outstanding issues from the audit along with conversations[6] that I had with Donna Bjurlin from Nestlé Corporate Quality with Mr. Zicher. Mr. Zicher stated that "her expectations were not realistic and that she was being picky."

After closer examination of the nonconformities, Creative Werks documentation, Nestlé requirements and the regulations, I discovered that her requests were directly tied to documents, procedures and analyses that would have resulted from a proper Food Safety Plan and other scientific risk based requisite and prerequisite programs, such as science risk based hazard analysis, Good Manufacturing Practices, ("hereinafter GMPs"), allergen controls, supply chain management, and Integrated Pest Management among other programs.[7]

For example, the Nestlé audit noted that Creative Werks failed to properly vet or produce evidence of proper receiving of products, even though it may have come from them initially (See Nestlé audit Exhibit 10).

To demonstrate that this was a common practice of not exercising proper food safety/defense, Mr. Zicher instructed me to not follow various requirements because the product was coming from Mondelez (See Exhibit 11).

Supplier verification is a requisite relative to food safety/defense. Further, Creative Werks purchased commodities from its clients that it packaged for sale and had a duty to ensure that food was safe and not adulterated before allowing it to be introduced into the stream of commerce for human consumption. Further, a Foreign Supplier Verification Program, ("hereinafter FSVP"), would be required when purchasing commodities outside of the United States for resale in the United States (See 21 CFR Subpart G).

There was no adequate mechanism in place nor did Creative Werks consistently follow whatever procedures it had in place relative to supplier verification (See Exhibit 12). Additionally, I had

[6] A longstanding biweekly meeting was held by Nestlé to address the outstanding audit deficiencies.
[7] The lack of a proper pest management program was evidenced by one (1) of the observations made by the FDA inspector on September 29, 2022 that noted there were pest control issues at both the Elk Grove and Bartlett facilities (See Exhibit 2 pg. 16 cross reference FDA July 2022 EIR 3010131930). The same observations were noted for sanitation and record keeping.

been instructed to release material that was being held for non-conformance based on this same premise on several other occasions.

**TRACEGAINS DOCUMENT REQUESTS**

I began reviewing TraceGains[8] requests for documents and searching for the requested documents from numerous clients. It was during this process that I began to fully understand that there were no specific documents relative to each client and their respective products. For example, one client was looking for a recall plan among other things. The only recall plan was for General Mills. The client was not General Mills (See Exhibit 13).

There were TraceGains requests dating back to 2021. These requests were not able to be fulfilled because of the lack of proper food safety plans, as well as compliance with customer requirements, prerequisite and requisite programs among other metrics. These requests mirror the audit deficiencies identified in the Nestlé audit.

Mr. Zicher makes a patently false and misleading statement in his declaration that the TraceGains requests at issue of almost 150 requests were a result of ongoing requests from a previous customer that no longer did business with Creative Werks (See Exhibit 14 pg.1).

The requests were made from various clients that were actively doing business with Creative Werks. Another example is Wilton Brands. Wilton Brands began requesting documents in 2021 and in October of 2022 began actively seeking these documents demanding to know why these documents were not being provided (See Exhibit 14 pg. 2)

The common practice had been recycling documents between customers to meet whatever requests, leading customers to believe that the documents provided to them by Creative Werks were inherent to their particular operation; when in fact they were not.

Customers relied on the information provided by Creative Werks for their business records and to demonstrate compliance with the FFDCA (FSMA) and relevant regulations as applied to food safety. For example, Nestlé was confronted with a compliance audit and had unmet past due deadlines of several months for outstanding audit deficiencies. I was contacted by Nestlé to provide updates and reasonable remediation steps. I reached out to Mr. Zicher and when he finally responded, he ignored issues that were a direct outgrowth or part of the mandated Food Safety Plans and other matrices or with non-relevant and noncompliant responses (See Exhibit 6).

[8] TraceGains is an online exchange platform for requesting, sending and receiving documents across the supply chain.

Further, I emailed Mr. Zicher about the voluminous document requests. I also told him I was uncomfortable with providing any false and misleading information to the customer based upon him previously instructing me to do so. TraceGains sent out a weekly status alert relative to documentation requests. Mr. Zicher was fully aware of the situation. Mr. Zicher once again has made patently false and misleading statements (See Exhibit 14).

**FOOD SAFETY PLANS**

I repeatedly asked Mr. Zicher about the Food Safety Plans and how they were constructed and what scientific basis was used. Finally, Mr. Zicher indicated that he used the Food Safety Preventive Control Alliance public draft edition participant manual that he received during training while working at Kraft as the basis for drafting the plan in addition to excerpts from the FDA template (See Exhibit 15).

None of these referenced documents supported how he derived the information referenced in his plan. There were also fundamental deficiencies with the document such as it being updated[9]. Even using the incorrect standard of HACCP, the application of the HACCP principles were still incorrect, as the severity/likelihood matrix did not support the information contained on the HACCP plan.

Mr. Zicher could not tell me the science, the method or point to any analysis to justify what was contained in the food safety plan he drafted relative to Dunkaroos that was to be the template for any other food safety plan (See Exhibit 15).

I explained to Mr. Zicher that such a plan was a cross-functional[10] document supported by process owners and other contributors founded on scientific principles such as Standard Operating Procedures[11] based upon scientific and standardized test methods and other fundamental principles, etc.

Creative Werks also lacked change control management, an essential function ensuring that various requirements are being met to remain compliant with FSMA and other relevant statutes. Further, change management is directly correlated to preventive controls such as validation, verification and reanalysis relative to 21 CFR 117 §§ 160, 165 & 170. This deficiency was also noted in the Nestlé audit (See Exhibit 10 CAR # 23)

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[9] Undated documents are in contravention of the record keeping requirements of 21 CFR 117.301.

[10] Cross-functional is defined as denoting or relating to a system whereby people from different areas of an organization work together as a team. Cambridge Dictionary https://dictionary.cambridge.org/us/dictionary/english/cross-functional.

[11] Creative Works did not have Standard Operating Procedures ("hereinafter SOP's). Work instructions were used instead. A number of these were stale dated.

**POSITIVE SALMONELLA**

During the week of October 24, 2022, it was discovered that there was positive testing for Salmonella at the Elk Grove facility. Prerequisite and requisite programs needed to manage such microbial hazards or any other hazards were not in place to reduce or mitigate the spread of these causative agents of food borne diseases. Nor did Creative Werks during the relevant time have any Standard Operating Procedures relative to microbial hazard management or any other biological, chemical, physical or radiological hazard.

Creative Werks handles Ready To Eat foods, ("hereinafter RTE") that lack any further processing or kill step to eliminate or reduce hazards. Therefore, it is incumbent that a science risk based analysis be implemented to manage identifiable and foreseeable risks to prevent food from being adulterated and introduced into the stream of commerce for human consumption (21 CFR 117).

It can easily be inferred that the consumer complaint filed in October of 2022 was a direct result of the lack of proper food safety and hazard analysis (risk management) at Creative Werks. The complaint was tied to cereal; a RTE (See Exhibit 16). More specifically, it can be reasonably inferred that the root cause of the reported October 2022 illness was due to Creative Werks willful failure to adhere to the mandate of food safety laws and regulations relative to ensuring that food is not adulterated when it enters into the stream of commerce (21 CFR 342).

**CREATIVE WERKS PURPORTED TO HAVE A SEE SOMETHING SAY SOMETHING POLICY.**

I drafted a very high-level risk analysis on October 20, 2022.

On the morning of October 21, 2022, I emailed Ms. Gretchen LeMay, VP of People and asked to speak with her on Friday October 21, 2022. We agreed to meet on that following Monday (See Exhibit 17). My intent was to speak with her about the outstanding issues described above.

On Friday afternoon, I spoke with Mr. Schroeder, the owner of the company regarding outstanding compliance issues and presented him with the risk analysis dated October 20, 2022 (See attached Exhibit 18).

During our conversation, Mr. Schroeder remarked that he did not understand what I was saying to be true because Erich told him that he worked at Kraft. I told him I could not speak to Mr. Zicher's actions, but that I was sure of what I was saying. I also told him that I had been formally trained and had years of experience with this kind of work. Mr. Schroeder also told me that I should have been trying to make nice with my boss since I had been there less than thirty (30) days.

It was my understanding that Mr. Schroeder would read the report and revert back to me for further discussion

Monday October 24, 2022 came and went and no one spoke with me nor did I have a meeting with Ms. LeMay.

On October 26, 2022, as I was leaving to go home, I was stopped, by Wendy from HR, and instructed to go into the conference room. It was at that time that Gretchen LeMay, VP of People, told me and presented me with a letter that I was being suspended for the conversation that I had with Mr. Schroeder (See Exhibit 19).

I was further told and it was memorialized in the same letter that an outside attorney would be conducting an investigation into the matters and allegations raised to Mr. Schroeder.

When I pressed Ms. LeMay on what grounds that I was being suspended on, she stated that my allegations were unfounded.

I offered her support of my position. I was instructed by her to save it for the attorney.

At no time after the conversation with Mr. Schroeder did he or anyone else follow up with me regarding the report. Nor was I involved in any type of investigation prior to being informed of my suspension.

I believe that my suspension on October 26, 2022 was in retaliation for my having presented the risk analysis to Mr. Schroeder. I also believe that I engaged in protected activity when I provided the risk analysis that detailed violations of the Food Safety Modernization and Bioterrorism Acts.

In further retaliation, I was not paid my sign on bonus on October 27, 2022 as referenced in my offer letter (See Exhibit 1).

After I requested to have an attorney present at the meeting with Creative Werks outside legal counsel, I was further retaliated against when my suspension transitioned from with pay to without pay (See Exhibit 20). Additionally, I was told by Ms. LeMay that I did not need an attorney because this was an in-house matter and the counsel would be acting in the capacity of an independent fact finder.

I communicated to Creative Werks the adverse employment actions, which were taken against me, including but not limited to being retaliated against for identifying and raising

non-compliance issues to Mr. Schroeder related to violations of FSMA. I further addressed the issue of not being afforded an opportunity to be a part of any investigation (Exhibit 21).

I requested my personnel file and it was provided on November 8, 2022 by Gretchen LeMay, VP of HR (See Exhibit 20). There was nothing in the file adverse except the suspension letter. I further reject the contention that I was not meeting Respondent's expectations and that they would have taken the same actions toward me. This is in direct contradiction to the fact that I was issued a written letter of suspension outlining the fact that my suspension was due to the conversation I had with Mr. Schroeder on Friday October 21, 2022 regarding the report dated October 20, 202 (See Exhibit 19). Further, according to Ms. LeMay there was nothing in the personnel file except the suspension letter and onboarding documents (See Exhibit 20).

Further, to date Creative Werks has not and cannot point to any non-retaliatory reason for suspending me. Nor can Creative Werks point to any company or public policy that I violated relative to my employment to warrant my suspension and de facto discharge/termination.

Further, Mr. Zicher publicly acknowledged in an email dated September 29, 2022, to management and the salaried associates of Creative Werks, that I had made positive contributions to the FDA audit (See Exhibit 4). Further, there was positive feedback from the Blue Diamond Growers audit indicating that it was an outstanding well-organized audit (See Exhibit 9). Further, Mr. Zicher also credited me for resolving a longstanding unresolved issue with Nestle (See Exhibit 10).

In regards to the non-conformances noted in the Blue Diamond Growers Audit, were issues that I had raised with Mr. Zicher on October prior to the audit and he indicated

I attended a meeting with the outside counsel on December 20, 2022, due to the meeting having to be rescheduled because of Defendants attorney becoming ill. Attorney Kim Ross of the Law Firm of Ford Harrison indicated that she was an independent fact finder. Attorney Ross is an employment lawyer, who did not demonstrate that she had an understanding of the subject matter contained in the risk analysis. We spoke for over 6 hours. Only an hour was spent talking about random excerpts of the report.

During the time we spoke, we talked about my background, past work experience and unrelated things to the issue at hand including the alleged after acquired evidence. It was also communicated to her that this investigation was contrived, a farce and a subsequent remedial measure to pretext.

In January of 2023, Creative Werks counsel contacted my legal counsel and made an offer of $50,000 indicating that I could not come back to work at Creative Werks because Eric Zicher could not work with me. He also indicated that my assertions and allegations were unfounded.

I requested my personnel file again to review the findings of the investigation that supported their contentions that my assertions were unfounded. Creative Werks declined to provide me my personnel file in contravention to the Illinois Personnel Review Act or the results of the investigation (See Exhibit 22).

Craig Thorstenson also of Ford Harrison stated that Creative Werks was claiming privilege and would not be sharing the findings based on client-attorney relationship. This explanation for denying me access to their findings contained in my personnel file belies the assertion that the outside counsel from Ford Harrison was acting as an independent fact finder.

Attorney Hoffman raised issue with Defendants claiming privilege. (See Exhibit 22)

Craig Thorstenson indicated that nothing new had been added to the Personnel file. (See Exhibit 22 )

Defendants admitted in their answer Dkt. #53 ¶95 that through my legal counsel, Creative Werks was again provided with my various theories of causes of actions, including but not limited to what I contend was retaliation amongst other things. I also contend that Creative Werks conspired to violate my protected rights. Creative Werks acknowledged that Creative Werks was aware of these theories and admonished me to make a counter offer, to their proposed severance offer, as they would not raise their offer until such time (See Exhibit 23).

I made a counter offer and their deadline to reply was April 17, 2023. Communications ceased and I filed my claim with OSHA on April 21, 2023.

Acceptance of Defendants severance offer was contingent upon me waiving any claims that I had against.

**RESPONDENT'S POSITION STATEMENT IN RESPONSE TO THE APRIL 21, 2023 WHISTLEBLOWER CLAIM**

I reject Creative Werks position on the matter at hand. First and foremost, Creative Werks is unable to support any of its assertions with relevant facts, rules, regulations or statutes to support their contentions, including but not limited to that I was terminated for incompetence.

To date Defendants have not been able to point to errors in the risk analysis that can be supported by fact, law or science.

I also categorically deny and vehemently disagree that I am incompetent.

Creative Werks has tried to convolute and malign the issue with facts that are not relevant and that are taken out of context relative to the fee waiver matter. To be extremely clear, I still contend that on that day and time when I applied I did not have the funding. Further, court records will show that I demonstrated this fact.

I further reject Mr. Zicher's assertion that I was hired to write the food safety plans. Further, the mere assertion that I was hired to write the plans underscores the fact that there were not any such plans. Further, Mr. Zicher does not point to anything to support this contention.

Additionally, the construct of a food safety plan is a cross functional and multidisciplinary function. Consequently, this contention could not be legitimate. Further, Creative Werks lacked the basic infrastructure, like standard operating procedures among other things, which Mr. Zicher alleged to be responsible for[12] to even begin developing such plans.

Hence the declaratory statement from Mr. Zicher is in contradiction to Creative Werks expert witness who claims that Creative Werks was compliant. Further, by Creative Werks own admission they lacked the requisite components of a food safety plan (See Nestlé audit CAR# 1 & 2). These two (2) competing interests and schools of thought create an unexplainable anomaly squarely putting Creative Werks in a conundrum.

I further reject the contentions of Creative Werks' expert witness who claims to be a Food Scientist, but yet in reality by her own admission on her LinkedIn page is only a microbiologist[13]. This claim of being a food scientist is disingenuous and patently false (See Exhibit 24).

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[12] See FDA REPORT 3010131930 dated July 14-15, 2022 pg. 6.

[13] According to the Bureau of Labor and Statistics: Food scientists and technologists use chemistry, biology, and other sciences to study the basic elements of food. They analyze the nutritional content of food, discover new food sources, and research ways to make processed foods safe and healthy. Food technologists generally work in product development, applying findings from food science research to develop new or better ways of selecting, preserving, processing, packaging, and distributing food. Some food scientists use problem-solving techniques from nanotechnology—the science of manipulating matter on an atomic scale—to develop sensors that can detect contaminants in food. Other food scientists enforce government regulations, inspecting food-processing areas to ensure that they are sanitary and meet waste management standards.

Bureau of Labor Statistics, U.S. Department of Labor, Occupational Outlook Handbook, Agricultural and Food Scientists, at Agricultural and Food Scientists : Occupational Outlook Handbook (visited August 3, 2023).

The Bureau of Labor and Statistics defines a Microbiologist as a person who "studies microorganisms such as bacteria, viruses, algae, fungi, and some types of parasites. They try to understand how these organisms live, grow, and interact with their environments."
Bureau of Labor Statistics, U.S. Department of Labor, Occupational Outlook Handbook, Microbiologists, at https://www.bls.gov/ooh/life-physical-and-social-science/microbiologists.htm (visited July 26, 2023).

Further, Dr. Knutson only has worked thirty-eight (38) months as a microbiologist in entry level positions in an industrial setting only performing routine tests, despite having a PhD according to her LinkedIn profile. Moreover, this work experience predates the enactment of any food safety law by almost ten (10) years. The concentration of Dr. Knutson's working career over the past two (2) decades seems to be centered around teaching and cannabis[14].

Further, if one is an expert, in any particular field of discipline, it would be par for the course, for the expert to be extremely familiar with governing rules, regulations, laws and best practices governing the subject matter and the rules of evidence to present such information. In addition to being able to apply them accurately and correctly as opposed to ignoring them or being in contravention of the very standards in which they allegedly contend to be proficient.

The FDA provides a rudimentary and basic understanding of the requirements and the statute outlined on the FDA's frequently asked questions webpage that is presented in non-technical and scientific terms that is available to everyone. Frequently Asked Questions on FSMA | FDA Further, by chance it happens to speak directly in detail about some of the issues that are in contention here.

For example, it clearly states that each facility needs a food safety plan and that each item requires a plan. Further, it is telling that Dr. Knutson did not take these and other factors into account in her analysis and that she could arrive at the conclusion she did predicated on the facts in this case.

Further, what is even more telling is that as a PhD recipient, scientist and alleged technical writer that Dr. Knutson either did not know or miserably failed to cite references in support of her theories or conclusions. This is a basic undergraduate scientific principle and even further a basic writing principle learned in grammar school.

Other telling indictments of Dr. Knutson's lack of understanding about food safety, HACCP and the precursor to HARPC and other matrices surround statements that she makes relative to the fact that there are no International Standards. One of the very things that she purports to be certified in is HACCP which takes direction from the Codex Alimentarius[15]an international standard. It is further common knowledge that FDA routinely adopts in full or in part food

[14] Schedule I controlled substance under federal law on par with LSD and heroin that is not federally regulated for human consumption.

[15] The Codex Alimentarius is a collection of internationally adopted food standards and related texts presented in a uniform manner. These food standards and related texts aim at protecting consumers' health and ensuring fair practices in the food trade. The publication of the Codex Alimentarius is intended to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization and in doing so to facilitate international trade. The United States has been a member of the Codex Alimentarius since 1963 (Members | CODEX ALIMENTARIUS FAO-WHO) (International & Interagency Coordination | FDA).

safety standards from the Codex Alimentarius (See Exhibit 25). Therefore, to espouse such patently false information is an indictment of sheer incompetence and unreliability. Dr. Knutson's actions are further reprehensible and unconscionable due to the fact that we live in an age where information is readily accessible and plentiful by just doing a simple Google search.

Further, Dr. Knutson nor Zicher nor Schroeder nor its counsel seem to understand that FSPCA is not the statutory and REGULATORY mandate outlined in the FFDCA as amended by FSMA.

They all further seem to specifically lack the understanding and the requisite knowledge that SQF and other third party audits are voluntary under the FFDCA and do not comport to compliance with FFDCA. (See Exhibit 26)

I further reject the authenticity of the alleged documents that Dr. Knutson reviewed because they were not attached as required for reference. Further, Creative Werks provided an incorrect job description that is not commensurate with the position in which I held.

I contend that Creative Werks conduct of providing an incorrect job description was deliberate, intentional and done in bad faith to support their erroneous contention that I was responsible for writing the Food Safety Plans "hereinafter FSP."

This conduct and practice of providing incorrect information is extremely telling and further supports other allegations of Creative Werks misconduct relative to providing non-relevant documents in an effort to skirt and avoid compliance with FSMA and the Bioterrorism Act of 2002. Additionally, I contend that this is an example of Creative Werks deliberate and willful actions to continue to retaliate against me and substantiate the adverse employment actions taken against me. Additionally, it further underscores Creative Werks pattern and practice of contrivances in this and other instances.

**UNSUPPORTED STATEMENTS**

Dr. Knutson chose not to support her findings by fact, law, science, peer review or even a blog. Based upon that choice, this expert opinion devolves down into a mere unsupported weak opinion based on inconclusive and conclusory statements.

I further reject Dr. Knutson's contentions that Creative Werks is/was compliant with the prevailing mandates based upon the twenty-six (26) documents reviewed by Dr. Knutson. Further, in sum, Creative Werks had in excess of twenty-six (26) customers who ran multiple food items that were wrapped, naked or blended. Creative Werks' three separate (3) facilities, purchased and resold commodities for human consumption, as well as manufactured contact and non-contact food grade packaging.

Additionally, it was well documented that Creative Werks did not have preventive controls in place, as PCHF rule had not been complied with. A requisite of compliance to an adequate food safety plan and the determinative factor of preventive controls. This was affirmed and evidenced by their own admissions. (See Nestlé audit pg.1) Conclusively, these facts do not demonstrate compliance or support her opinion.

Further, as an alleged consummate expert in food safety, Dr. Knutson should have known immediately that the absence of such documents like hazard analysis, preventive controls, supply chain program, vulnerability assessment etc… does not comport with compliance. Dr. Knutson should have further known as a microbiologist that "RTE" foods that are handled and stored require an analysis to determine any associated hazards and then how to manage the risk (preventive controls). A failure to do so is a dereliction of the duty of care imposed upon Creative Werks to ensure food that is introduced into the stream of commerce is safe for human consumption and not adulterated in accordance with 21 CR 342.

Even if Dr. Knutson did not know anything else this concept would or should have definitely been in her wheelhouse as a degreed PhD Microbiologist. Sadly, this is a fundamental concept that is taught on an undergraduate level. Dr. Knutson's inability to reconcile this principle with her education and her boasting of having taught an approved curriculum over forty (40+) plus times is testament to her sheer incompetence in food safety even from a scientific perspective.

I hired an expert witness, Dr. Katherine Adams Hutt, to rebut Defendants opinion (See Exhibit 27)

Dr. Hutt is a consummate professional and expert in Food Safety Regulations and contributed to the framework of the Food Safety Regulations.

I further reject the contention that I lacked professionalism relative to speaking with the owner.

First and foremost, the company and its owner touted a mantra of a "see something say something[16]" policy that they continuously reiterated in meetings and by post.

Further, the owner on an ongoing and regular basis spoke with his employees daily about a myriad of things. He himself espoused transparency among other things and had personally on several occasions stated that he hoped that I was helping the company along.

It was with great trepidation that I approached Mr. Schroeder even after having contemplated a backlash as a response, as evidenced by my request to speak to Ms. LeMay. However, I could not reconcile in my mind how someone who builds a successful business, purports to care about

[16] The FDA inspector makes note of this policy and references it in her report See Exhibit 2 pg. 16.

their employees, tries to create a decent and palpable work environment, engages in philanthropic efforts and makes himself available and accessible to his employees would want to find themselves blindsided, hoodwinked and bamboozled about their operation. Notwithstanding being flogged with possible criminal charges and economic woes.

Further, as Dr. Knutson noted, I am held to a higher standard and I learned relatively quickly that the standards were not being met. Additionally, being held to a higher standard and being a leader means that you have to be accountable for your actions and inactions. Conversely, if something adverse had occurred without a doubt the scenario would have been "you should have known better and you should have said something."

Additionally, there are a number of instances within the industry that have occurred as a result of people not following the standards. e.g. Blue Bell creameries and Peanut Corporation of America are prime examples of companies not following basic safety rules. In particular, it was noted in a Press Release from the Department of Justice in July of 2020 that the Blue Bell Creameries Listeria case "was particularly concerning because of the disregard of basic food safety rules and the impact those actions can have on the health and safety…" according to Robert E. Craig Jr., Special Agent in Charge of the Defense Criminal Investigative Service Mid-Atlantic Field Office.

The Press Release also went on to say:

"The health of American consumers and the safety of our food are too important to be thwarted by the criminal acts of any individual or company," said Judith A. McMeekin, Pharm.D., Associate Commissioner for Regulatory Affairs, FDA. "Americans expect and deserve the highest standards of food safety and integrity and we will continue to pursue and bring to justice those who put the public health at risk by distributing contaminated foods in the U.S. marketplace."
https://www.justice.gov/opa/pr/blue-bell-creameries-agrees-plead-guilty-and-pay-1935-million-ice-cream-listeria

Another press release from the Department of Justice, relating to a supply chain recipient of the tainted peanut butter from the Peanut Corporation of America, predating the Food Safety and Modernization Act of 2011 underscores the long time initiative and commitment of the FDA to food safety.

"Product safety has to be a high priority for every manufacturer of foods sold in the United States" says Stephen M. Ostroff, Deputy Commissioner for Foods and Veterinary Medicine at the FDA. "FDA is working with food producers to promote compliance with food safety

requirements, but if problems occur and are willfully ignored, we will use all available resources to protect American consumers from unsafe food."

https://www.justice.gov/opa/pr/conagra-subsidiary-sentenced-connection-outbreak-salmonella-poisoning-related-peanut-butter

Further, as a consumer, I am concerned about the health and welfare of myself, my family and society at large, as the products that are handled at Creative Werks are common brand name, brand leading, household foods that people of all ages consume. Further, these products are not typically flagged to be high-risk consumption foods to alert vulnerable populations such as infants, children, pregnant women, the elderly or immunocompromised persons that can be adversely affected by the causative agents of food borne illness or disease.

**THE LACK OF ISSUANCE OF A FDA FORM 483 DOES NOT OBVIATE THAT INFRACTIONS AND OR VIOLATIONS OF THE FOOD DRUG AND COSMETIC ACT OCCURRED AND WERE OBSERVED BY THE FDA**

It is well established and documented that the FDA inspector observed, noted and made five (5) observational findings in contravention of the FFDCA (FSMA) (See Exhibit 2).

Mr. Zicher touts the fact that a 483 was not issued, but does not exhibit the presence of mind to understand the severity of the findings or he intentionally minimizes the occurrences. Additionally, the FDA inspector pointed out that there seemed to be a systemic problem related to the record keeping, facility maintenance (dock doors)[17] and pest control due to the fact that the same issues identified at Bartlett in October of 2022 were also noted from her July 2022 inspection of the Elk Grove facility (See Exhibit 2 pg. 9).

Again, the lack of proper prerequisite and requisite programs underscore the observations made at both Elk Grove and Bartlett Creative Werks facilities, as well as the Nestlé audit findings.

MR. ZICHER'S CLAIMS OF BEING A DEGREED BIOCHEMIST AND/OR A B.S. IN SCIENCE

Mr. Zicher claims on his LinkedIn page to have a BS in science and at other times a BS in Biochemistry (See Exhibit 28 and Exhibit 29). This conduct of purporting to have a degree that he does not have or skills that he cannot evidence is egregious and unconscionable at best.

Further, this assertion of having a BS in Biochemistry is telling and is juxtaposed to the subpar quality of knowledge evidenced in his work product relative to even creating the HACCP plan

[17] Nestlé noted the deficiencies in the dock doors in their audit.

for the Dunkaroos non-compliant food safety plan. Mr. Zicher's overall approach to drafting the non-science-risk based document does not support his claim(s) of having a B.S. in Science let alone a B.S. in Biochemistry.

It is not likely and highly improbable that a degreed science major from an accredited institution in any applied science should lack fundamental concepts of scientific principles such as following established standardized methods. Nor should they lack basic understanding of the requests made by the FDA inspector in regards to record keeping or how to apply basic high-school science concepts to science risked based initiatives.

What is even more telling of Mr. Zicher's competency is that Mr. Zicher an alleged degreed Biochemist or some other degreed science major could not, did not and has not spoken to the issues raised relative to the non-conformities himself in any manner-lay, technical, scientific or otherwise.

Specifically, Mr. Zicher in no formidable way has ever rejected my contentions, provided any documentation, law, facts, peer review or by any other means or instrument been able to contradict or refute the actual issues that I raised. Further, he was unable to demonstrate how he reached the conclusions he asserted utilizing appropriate technical and scientific terms and principles to refute, reject or contradict the issues that I raised. This lack of responsiveness in a scientific professional manner is telling.

Additionally, Mr. Zicher never provided an action plan, inclusive of a plan of action, expectations, goals or any direction on how to approach remediating the outstanding customer and regulatory issues.

Mr. Zicher's same LinkedIn page does not support that he ever worked at Kraft as alleged. Mr. Zicher is not credible nor is he a qualified person by education, training and or job experience or a combination thereof as defined by the FDA (21 CFR 117.3) to function in the supervisory capacity of Director of Food Safety that he is operating in. (21 CFR 117.4(c))

Further, allowing someone to infiltrate the organization through a perpetration of "working at Kraft" or alleging to have a "BS in Biochemistry" is another indictment of Creative Werks inadequate food safety and defense programs and its inherent ability to comply with FSMA and the Bioterrorism Act of 2002 that require employers to vet their employees. 21 CFR 117.4 (a)

My intention was to steward closure to the compliance gaps at Creative Werks that had existed since the PCHF rule had been implemented in 2015, but was never complied with by Creative Werks[18]. Moreover, my hope was to create and build robust food safety and defense programs

[18] Creative Werks was non-compliant prior to Mr. Zicher becoming the Food Safety Director in 2020.

that attract and retain customers and to avoid negative goodwill and minimize any potential liability that may have resulted from the consumer complaint investigated by the FDA or any other complaint.

POST DOL Filing

I did not become aware that my suspension without pay (de facto termination) had transitioned to an official termination until Defendants had responded to the Department of Labour complaint in July of 2023.

Defendants for the first time asserted that I was incompetent and that was the basis for the alleged termination (See Exhibit 30).

I reject the contention or assertion that I am incompetent.

This is in contravention to the reasons asserted in the District Court for termination. The reason asserted for termination was after acquired evidence and/or policy violations. (DKt. #53 pg. 34 Affirmative Defense 2 & 3)

This reason also differs from the reason given to the IDHR for termination (See Exhibit 31).

Defendants, VP of HR, Gretchen LeMay, also told the IDHR that Plaintiff's suspension was moved to unpaid after I refused to respond to her calls (See Exhibit 31 2/29/24 witness interview, Gretchen LeMay) Exhibit 20 is a group exhibit of emails from November 1, 2022 through November 8, 2022 specifically with Gretchen LeMay who transitioned me to a non paid suspension.

Specifically, Gretchen LeMay emailed me on November 1, 2022. I responded back to her email on November 2, 2022. LeMay responded on November 2, 2022. I also responded on November 2, 2022. LeMay responded on November 3, 2022. I responded on November 4, 2022 and against on November 7, 2022 twice and LeMay responded back on November 8, 2022, informing of the transition of my suspension from paid to non-paid (See Exhibit 20)

LeMay also told the IDHR that I never reported adverse employment actions to Defendants See Exhibit 31. This is in contradiction to Defendants' judicial admission that says otherwise. Dkt. #53, pg. 29, ¶95

LeMay also provided false and misleading information to the IDHR (See Exhibit 31) as to what my job responsibilities were in contravention to Defendants' admissions in their answers indicating that Plaintiff was responsible for regulatory and compliance. Dkt. #53, pg. 7, ¶8

LeMay also stated to the IDHR (See Exhibit 31) Plaintiff's report that was presented to the President included defamatory remarks regarding leadership.

To date, LeMay nor Defendants have been able to identify any defamatory remarks or errors of fact, law and science.

Defendants have knowingly been providing false, misleading and inconsistent information to various governmental agencies.

I have not been formally terminated by Defendants. I requested my personnel file twice; once in November of 2022 and again in January of 2023. Defendants admitted that there was not anything in my personnel file to support poor performance or termination and that no documents were withheld. Dkt. #53 pg. 28 ¶92

Defendants represented in open Court on the hearing of Plaintiff's Rule 11 motion that Defendants previous legal counsel of Ford Harrison represented to Plaintiff's legal counsel, Attorney Hoffman, in the Department of Labour matter that Plaintiff had been terminated.

I reject that contention as Mr. Hoffman at no juncture has represented to me that he has been notified that I had been terminated by Craig Thorstenson or any representative from the Law firm of Ford Harrison. See Exhibit 30 Declaration of Jordan T. Hoffman

Defendants were aware that Plaintiff did not have termination claims before the court and acknowledged and agreed to remove such language from the initial disclosure report that it was to prepare and file with the court. See Dkt. 41

Defendants attorney also told Plaintiff that she was not to police his litigation strategy (See Exhibit 32).

I, Mary Madison, declare under penalty of perjury that the foregoing is true and correct.

Dated: June 19, 2025 /s/ Mary Madison

Exhibit 1

creative werks
1470 Brummel Ave
Elk Grove Village, IL 60007
www.creative-werks.com
630.860.2222

September 20, 2022

Mary Madison,
Via Paycor– assist2law@gmail.com

Dear Mary,

I am very pleased to offer you the opportunity to join our team at creative werks. We believe that you will find working at creative werks challenging, fun, and a great opportunity to learn. Fit is key for us and we believe that your contributions and work ethic will help our Company grow and flourish.

We would like to confirm the arrangements made regarding this opportunity. We are very happy to offer you a position as a **Quality Regulatory Manager**, at our ***Elk Grove Village***location on ***1st Shift*** within our **Quality** department. This position will be reporting to Erich Zicher (Food Safety Director) starting on September 27, 2022.

**Compensation**

- You will be paid a Salaried Exempt rate of $3,653.85 paid bi-weekly ($95,00 annually) so long as you are actively employed by the Company.

**Annual Incentive Plan (AIP)**

- You will be eligible to participate in creative werks 2023 Annual Incentive Plan (AIP) with a target incentive of 10% of your salary. The AIP is based on a combination of company performance, individual performance, and target incentive. The 2023 AIP will be payable in March 2024. Please refer to the AIP document for specific plan details.
- As discussed, we are pleased to offer you a signing bonus of $2,500 payable in one lump sum on October 27, 2022. This signing bonus is taxable, and all regular payroll taxes will be withheld. In the event that you leave creative werks within 12 months of your date of hire, you will be responsible for reimbursing the company for the entire signing bonus. By your signature on this employment agreement, you authorize the company to withhold $2,500 from any severance and other final pay you receive should your employment terminate on or before October 27, 2023

**Paid Time Off (PTO) and Holiday Pay**

- You will accrue PTO at the rate of 16 days per year (2.46 hours per week).
- For 2022, since you are starting later in the year, you will be eligible for 4.5 days of PTO.
- As a CW associate you will receive 9 paid holidays throughout the calendar year.

creative werks
1470 Brummel Ave
Elk Grove Village, IL 60007
www.creative-werks.com
630.860.2222

**Code of Ethics, Values and Policies**

- creative werks is committed to creating a positive environment and conducting business ethically. As an associate of the Company, you will be expected to abide by our Guiding Principles and general policies and practices set forth in our Employee Handbook.

After you return this signed offer letter, you will receive two emails from Paylocity. Paylocity is our onboarding tool which contains various online documents such as benefit forms, tax forms, a participation release form, an emergency contact form, confidentiality agreements, a background check, an employment eligibility form (I-9), and information about the Health Insurance Portability and Accountability Act. Please complete these documents as soon as you can. We need these completed in advance of your start date so we can be prepared for you when you arrive.

Please note that this offer is contingent upon successful completion of the background check and compliance with all new hire forms.

Mary, your signature below will acknowledge that there have been no representations by the Company or its agents which are not reflected in this letter. Please review all terms of this letter, returning the signed original to me by September 23, 2022

I am pleased you have decided to join creative werks. I look forward to watching your progress with the Company.

Sincerely,

*Gretchen LeMay*

Gretchen LeMay
Head Of People / Corporate VP

Mary Madison1 cef

_____
Mary Madison

September 20, 2022

_____
Date

Exhibit 2



## Table of Contents



## Summary

This pre-announced comprehensive routine surveillance inspection of a warehouse, packer/repacker, labeler/Relabler and distribution center (DC) was performed as part of HAF 6 EAST FY-2022 Workplan in MARCS/eNSpect as OP ID-#226878. This

inspection was accomplished utilizing CFR-21, Part 117 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Control for Human Food – Subparts A, B, and F along with Compliance Program 7303.040, Preventive Controls and Sanitary Human Food Operations. In addition to CP 7321.005 Domestic NLEA and General Food Labeling Program.

Creative Werks LLC functions as a warehouse, packer, repacker (Co-Packer), labeler, Relabler, and DC. The firm's top three customers are (b) (4) (b) (4). The firm's top three products at this location are (b) (4) (b) (4).

This firm store, packs/repacks (Co-Packs), labels/relabels a variety of wrapped and unwrapped ready-to-eat food products per their customer request. After packing/repacking, labeling/relabeling and final packaging is completed, the finished product is scheduled to be shipped to one of their customers distribution centers as specified by their customer.

***Previous inspection***

The firm has never been inspected by the Agency. This was the firm's initial inspection.

***Current Inspection***

This inspection was classified as NAI. Although, the firm was not issued an FDA Form 482 at the close of this inspection. The following concerns were discussed in detail with management as follows:

1. I observed light seeping through dock door #5 during the walk-through.
2. I observed that the firm is not consistent with recordkeeping after reviewing training documents.
3. I observed that the consumer complaint investigation for consumer complaint #170623 should have had a faster response.
4. I observed that the firm's pest control activities are inconsistent and needs work.
5. I observed a production employee cleaning equipment located along the north wall adjacent to Production Line (b) (4) with a long white towel using his right hand to touch the floor for balance and alternating the towel in his right hand as he cleans the conveyor equipment on top.

Management Response:

Mr. Zicher promised to make corrections to the observations as soon as possible.

This inspection focused on the following areas: Sanitary Transport, Sanitation, Raw Materials, Recalls, Customer Complaints, Pest Control, Quality Control, Sales, Production, Purchasing, Recordkeeping, and Employee Training.

I did not notice any avian, insect and/or rodent activity during the inspection.

I did not take any samples and/or photos during this inspection.

(b) (3) (A)

I did encounter one refusal during this inspection which converted to an electronic view of consumer complaint #170623 for closure.

**Consumer Complaint #170623 Follow-up** – (b) (4) (b) (4) Cheese Snacks- 20 ounce (1.4 rigid plastic container with screw chalking). Product of (b) (4)

*Consumer Complaint:* This consumer complaint dealt with a consumer becoming ill after consuming (b) (4) Cheese Snack. The customer identified a black substance found around the lid as mold.

Corrective Actions as provided by the firm (Identification of Root Cause):

| Issues | Resolution | Date Accomplished |
|---|---|---|
| Slippage experienced with the lid torque. | Custom built machine chuck was installed to replace the silicone rubbing head & reduce any slipping in the lid application. | 3/22/2021 |
| Multiple passes with a barrel through the induction sealer caused burning of the film stock. | Production Team discontinued sending barrels through the sealer more than once. | 5/20/2021 |
| Settings for induction sealing equipment not documented. | Documented settings were recorded & posted on the line for the Maintenance Team. | 6/6/2021 |
| Reject cylinder & rails caused barrels to jam. | Section of rail was removed to prevent jars & counting sensors was relocated. | 6/7/2021 |
| Lid cocked sensor process had poor repeatability. | Adjusted & documented location of cocked lid sensor. Tested in various orientations. | 6/6/2021 |

*Additional Complaints:* According to Mr. Erich P. Zicher, Director of Food Safety the firm had only one similar complaint sent by (b) (4) on March 13, 2022 regarding a burnt seal. In addition, Mr. Zicher told me he was not aware of any other complaints.

*Findings:* According to the firm's findings the induction seal for the lid was burnt due to multiple entries of the lid passing through the induction (heat) sealer. It was documented that during manual application of the lid the firm experienced jams on the production line which also resulted in burnt lids.

*Packaging Procedure:* The packaging procedure for this product was modified on May 20, 2021 as document in the firm's step-by-step corrective actions/investigation listed above.

*Preventive Controls:* The firms preventive control consisted of the removal of manual application of the lid to a (b) (4) lid application to remove the variation out of manually applying the lid. According to the firm the new machinery was approved by (b) (4)

*Product's Current Disposition:* According to Mr. Eric P. Zicher, Director of Food Safety, the firm currently is not repacking (b) (4) Cheese Snacks for (b) (4) . The contract for packing this product is stagnant until there is a negotiated procedure for lid application for this ready-to-eat product.

## Administrative Data

***FMD-145***

A copy of this EIR should be sent to the individual listed below:

Mr. Erich P. Zicher, Director of Food Safety
Creative Werks, LLC
1460 Brummel Avenue
Elk Grove Village, IL 60007
Email address: ezicher@cwerksglobal.com

**Inspected Firm:** Creative Werks, LLC
**Location:** 1350 Munger Rd.
Bartlett, IL 60103

| | |
|---|---|
| **Phone:** | (630) 860-2222 |
| **Fax:** | None |
| **Mailing Address:** | 1460 Brummel Avenue<br>Elk Grove Village, IL 60007 |
| **Email Address:** | ezicher@cwerksglobal.com |
| **Dates of Inspection:** | September 28, 2022 & September 29, 2022 |
| **Days in Facility:** | 2-Days |
| **Participant:** | Clotia C. Abbey-Mensah, Investigator |

On September 28, 2022 I presented credentials and issued an FDA Form 482 Notice of Inspection to Mr. Eric P. Zicher, Director of Food Safety who identified himself as the person most-in-charge. We were joined by Ms. Angela K. Knabe, Quality Regulatory Manager, Ms. Anupam (N.M.I,) Sharma, Food Safety & Quality Manager, and Ms. Mary D. Madison, Quality Regulatory Manager. Throughout this inspection I was provided documents for review as requested by Mr. Zicher and Ms. Sharma. I was accompanied on a tour of this facility by Mr. Zicher and Ms. Sharma.

## History

Creative Werks is located at 1350 Munger Rd. in Bartlett, IL 60103 in DuPage County. The firm is owned by Mr. Steven A. Schroeder, President. I asked Mr. Zicher if Mr. Schroeder maintain an office at this location and he responded no. The firm has been in business since 1999 and at this location since May 2015.

The firm is (b) (4) square feet (sq. ft.). Of this square footage (b) (4) is considered manufacturing per Mr. Zicher. This firm store, packs/repacks, labels/relabels a variety of wrapped and unwrapped ready-to-eat food products per their customer request.

The firm's telephone is (630) 860-2222. The firm has (b) (4) employees at this location. This number includes hourly, salary and temporary employees per Mr. Zicher.

The firm has two other locations as listed below:

| Headquarters/Production Facility | Warehouse/Production Facility |
|---|---|
| Creative Werks, LLC | Creative Werks, LLC |
| 1460 Brummel Avenue | 222 Sievert Court |
| Elk Grove Village, IL 60007 | Bensenville, IL 60106 |

The firm's office hours are 8:00 am to 5:00 pm Monday – Friday. The firm's production hours are (b) (4) according to Mr. Zicher. The shifts are scheduled as follows:

(b) (4)

The firm runs manufacturing and co-packing on all (b) (4) shifts per Mr. Zicher. The firm does not have scheduled shutdowns for preventative maintenance. According to Mr. Zicher one of the firm's main functions is private labeling.

The firm's FY starts on January 1st and ends December 31st annually. The firm's website is www.creative-werks.com. The firm's email address is ezicher@cwerksglobal.com.

**Interstate (I.S.) Commerce**

I asked Mr. Zicher what percentage of the finished products at this location cross state lines. He responded (b) (4). I asked what percentage of the finished product is sold wholesale. He responded (b) (4). Lastly, I asked what percentage of components are received through interstate and he responded (b) (4). I requested a copy of a BOL for (b) (4) which was not provided.

The firm does business with their customers Distribution Centers (DCs) domestically and internationally as listed:

1. California
2. Georgia
3. Indiana
4. New Jersey
5. Pennsylvania
6. Texas

7. Utah
8. Wisconsin
9. Alberta – Canada (Calgary)
10. Ontario – Canada (Brampton)
11. Ontario – Canada (Mississauga)

## Jurisdiction (Products Manufactured and/or Distributed)

This firm packs/repacks, labels/relabels a variety of ready-to-eat food products such as chocolate candy, cereal, chewing gums and snack foods etc.

## Individual Responsibilities and Persons Interviewed

On September 28, 2022 I presented credentials and issued an FDA Form 482 Notice of Inspection to Mr. Eric P. Zicher, Director of Food Safety who identified himself as the person most-in-charge. We were joined by Ms. Angela K. Knabe, Quality Regulatory Manager, Ms. Anupam (N.M.I,) Sharma, Food Safety & Quality Manager, and Ms. Mary D. Madison, Quality Regulatory Manager. Throughout this inspection I was provided documents to review as requested by Mr. Zicher and Ms. Sharma. I was accompanied on a tour of this facility by Mr. Zicher and Ms. Sharma. I requested a copy of the firm's organizational chart during this inspection. (See Exhibit #1)

*Responsibilities:*

Mr. Eric P. Zicher, *Director of Food Safety*

- Food Safety & Quality
- Escalates Issues
- Environmental Issues
- Projects – (Ongoing, New)
- Identifying Potential Quality Risks
- Microbiological Aspects with Products
- Write SOPs (Work Instructions, Policies, etc.)
- Hire/Fire
- Strategic Directives for Container Safety
- Food Safety & Quality
- Time with firm: 1.9 years
- Time in current position: 1.9 years
- Direct Reports: [redacted]
- Reports to: Mr. Ronald Sammeth, *Chief Operating Officer*

Ms. Angela K. Knabe, *Quality Regulatory Manager*

- Audits (Clients POC for Audits)
- Lead Good Manufacturing Practice (GMPs) Walk
- Ensuring Compliance (Corrective Actions)
- Vendor Approvals
- Quality Management Systems - (PCQI)
- Time with firm: 3.5 years
- Time in current position: 2 years
- Reports to: Mr. Eric P. Zicher, *Director of Food Safety*

Ms. Anupam (N.M.I,) Sharma, *Food Safety & Quality Manager*

- Discussion of Food Safety holds with Sales Personnel
- Certificate of Analysis (COA) Reviews
- Packaging Reviews
- Raw Materials Packaging; Film Review
- Hold Releases
- Operational aspects within Specifications
- Timecards
- Employees Issues
- Releasing product after review of COA
- POC for Food Safety /Food Compliance
- Assist with SOPS by other departments
- GMP Training provided to Operations, Sanitation Materials Handlers and Quality Control Employees
- Sending out samples for testing
- Time with firm: 1 year
- Time in current position: 1 year
- Direct Reports: [redacted]
- Reports to: Mr. Eric P. Zicher, *Director of Food Safety*

Ms. Mary D. Madison, Quality Regulatory Manager

- Audits (Clients POC for Audits)
- Lead Good Manufacturing Practice (GMPs) Walk
- Ensuring Compliance (Corrective Actions)
- Vendor Approvals
- Quality Management Systems - (PCQI)
- Time with firm: 2 days
- Time in current position: 2 days
- Reports to: Mr. Eric P. Zicher, *Director of Food Safety*

## Firm's Training Program

I asked if the firm provide any training to their employees and the response was yes. Training is provided to employees upon hire and annually. Ms. Sharma told me that the firm use (b) (4) software for training. The software divides the various training modules into specific topics such as Food Safety, Foodborne Illnesses, Guidance Principles etc. I asked Ms. Sharma if the employees sign-off on training and she responded yes. During this inspection I randomly reviewed employees training records that appeared to be adequate except the firm's recordkeeping is not consistent. All employees do not consistently sign-off on training records as required in their own procedure with a signature and date, which is deemed an official document. This observation was shared with Ms. Sharma during this inspection. This was an observation previously observed at the firm's Elk Grove Village facility.

I requested a copy of management training records during this inspection. (See Exhibit # 2)

## Manufacturing Design Operations

This firm packs/repacks and labels/relabels ready-to-eat products such as candy, cereal, cookies, and gums, etc. for their clients.

***Donning Area/ Handwashing Station***

Prior to entering the manufacturing area, a visitor is required to wear the following PPE: hairnet, ear plugs, laboratory coat, safety vest and safety googles. The firm identifies individuals in production as follows:

| (b) (4) | | |
|---|---|---|
| Management | Visitors | Quality Control |

After donning is completed, you proceed to the handwashing station, located adjacent to the employee's break room.

***Ambient Warehouse***

The firm's warehouse aisles on the south-side mid-way are labeled (b) (4) The north-side of the aisles are labeled (b) (4)

***Dock Doors***

The firm has (b) (4) dock doors at this location. Two of the (b) (4) are not in use. Dock Door (b) (4) contains the firm's compactor. Dock Door (b) (4) is used to store equipment. The firm's dock doors are grouped into (b) (4) as follows: (b) (4) and (b) (4). I observed that dock door #5 has sunlight seeping in. I shared this observation with Mr. Zicher and Ms. Sharma during the walk-through.

***Production Area***

The firm has (b) (4) active production lines. Currently the firm is actively using (b) (4) production lines. Some production lines are in segregated rooms. Some production areas can have several production lines packing a variety of products in the same room.

The firm's sanitation area is (b) (4). I observed a walk-in equipment washer from the outside looking in. The doors to this area were locked but I could see from the outside mostly covered cleaned production parts and equipment.

**Lines (b) (4) – Repacking**

I observed a production employee cleaning equipment located along the north wall adjacent to Production Line (b) (4) with a long white towel using his right hand to touch the floor for balance and alternating the towel in his right hand as he cleans the conveyor equipment on top. This observation was immediately shared with Mr. Zicher and Ms. Sharma during the walk-through. I noticed a similar action with a production employee at the firm's Elk Grove Village location.

This area is also used for storing production equipment and supplies.

I observed (b) (4) packed on these lines in a clear plastic holiday cane. (See Exhibits #3-5)

***Sanitation Area***

In the next section of the contained sanitation area, I could see compartment sinks. I observed a (b) (4) compartment sinks. I asked what the (b) (4) compartment sink is used for. I was told it is used for washing and sanitizing. There appears to be no rinse step for the (b) (4) compartment sink. I could also see (b) (4) frosting pump equipment through the exterior sight windows.

The east wall in this area houses the maintenance department, and employee entrance.

**Line (b) (4) – Whole Packing**

I observed (b) (4) Tubes packed on this production line.

**Line (b) (4) (Naked)**

I observed naked (unwrapped) candy been packed in tubes on this production line. The tubes are equivalent to clear plastic candy canes.

**Line (b) (4)**

I observed (b) (4) been packed in the cereal room.

**Lines (b) (4) Line)**

I observed (b) (4) candy containing peanuts repacked on this production line. The firm only runs peanut production on these lines.

**Line (b) (4)**

This line packs chewing gum. It was currently not in operation during the walk-through.

**Lines (b) (4)**

I observed (b) (4) packed on these lines in a clear plastic holiday cane.

***HACCP Plan***

I asked Mr. Zicher if the firm has a HACCP Plan and he responded yes. Ms. Angela K. Knabe, Quality Regulatory Manager is responsible for the firm's Quality Management System (QMS). Time did not permit me to verify the firm's entire food safety plan during this inspection. Ms. Knabe identified herself as the firm's PCQI. This responsibility will soon be delegated to Ms. Mary D. Madison because Ms. Knabe is leaving the firm next week. The firm also have x-ray equipment in place as a process preventive control.

***Metal Detectors***

The firm documents their metal detector every (b) (4). This information was not verified. This is the firm's only critical control point (ccp) in their process. The firm's metal detectors are calibrated by (b) (4). located at (b) (4) (b) (4). Their telephone number is (b) (4). The firm's website is (b) (4).

***Leak Detector***

I asked Mr. Zicher if the firm performs leak detection at this facility and he responded yes. The leak detection is performed on the cereal production line. This information was not verified.

***Raw Materials***

The firm's raw materials consist of clear plastic candy canes, cane handle, product labels for packaging, wrapped candy products, plastic bags, cereal bowls, cardboard boxes, etc.

***Allergens***

I asked management if the firm has any allergens onsite and their response was yes. The allergens consist of eggs, wheat, soy, dairy, peanuts, and tree nuts per Ms. Sharma. The firm may handle allergens contained in wrapped or unwrapped packaging. I asked Mr. Zicher what preventive controls are in place to prevent cross contamination. He responded sanitation is used to prevent cross contamination and production takes place in cycles. The firm also performs ATP swabbing prior to production per Ms. Sharma. This information was not verified.

***Internal Audits***

I asked Mr. Zicher if the firm performs internal audits, and he responded yes. The firm performs internal audits annually. This information was not verified. In addition, Ms. Knabe told me that she leads GMP (b) (4) walking audits of the facilities and Food Safety meetings.

***Sanitation***

I asked Mr. Zicher if the firm has a Sanitation Standard Operating Procedure (SSOP) and he responded yes. I randomly reviewed the firm's SSOP- #6.15 effective June 21, 2022, and it appeared to be adequate. I asked who provides sanitation training and I was told Supervisors, Assistant Supervisors and Team Leads.

***Sanitary Transport***

The firm has a sanitary transport SOP WI-5,2 that includes (b) (4)-conditions which is uploaded into their database via their (b) (4) software. After review of the firm's sanitary transport SOP, it appears to be adequate.

***Logistics***

The firm's customers broker trucks for transporting their products. The customers arrange product loads inbound and outbound of their facility. Some customers use their own fleet of trucks. Regardless per Mr. Zicher the truckers must make appointments for pick-ups and deliveries.

***Environmental Controls***

I asked management if the firm has an environmental control program, and the response was yes. I reviewed the firm's SOP and it appeared to be adequate. The firm's program is sectioned into (b) (4) -Zones. Zone (b) (4) (food contact surfaces) per Ms. Sharma is cleaned and sanitized. The firm sends out samples for APC and E. coli as validation for sanitation. Zones (b) (4) are swabbed with sponges and sent out for Salmonella and Listeria species testing. The samples are sent to (b) (4) (b) (4) located in (b) (4) I asked who performs the swabbing and Ms. Sharma responded the Quality Supervisor, Team Lead and Quality Manager.

***Water***

I asked Mr. Zicher if the firm monitor the water for the city of Bartlett. Mr. Zicher responded yes. A copy of the city's annual test results was shared on the firm's overhead screen. Additionally, the firm collects and sends out (b) (4) water samples for Heterotrophic and coliforms.

***Refuse***

The firm's refuse is serviced by (b) (4) is located at (b) (4) (b) (4) . The firm's telephone and website are (b) (4) and (b) (4) respectively.

The firm's recyclables and landfills are also maintained by (b) (4) . The recyclables consist of corrugated and plastics polymers such as (b) (4) .

## Manufacturing Codes

I asked Mr. Zicher to decipher the firm's manufacturing code as follows:

(b) (4)

(b) (4)

(b) (4)

## Complaints

I requested a copy of the firm's consumer complaint procedure during this inspection for review. The firm's consumer complaint is identified as WI-2.6 with an effective date of May 21, 2019.The firm's complaint procedure appears to be adequate. I asked Mr. Zicher if the firm performs trending, and he responds yes. Because the firm co-packs for their clients there is a relationship between Creative Werks Quality personnel and their client's Quality Contact per Mr. Zicher. I asked how investigations are performed. Mr. Zicher told me that after an investigation is completed a corrective action is provided when the root cause is determined.

## Recall Procedures

The firm has a recall procedure reference as Traceability. According to Ms. Sharma the firm performs trackabilities (b) (4) . I randomly reviewed the procedure, and it appears adequate. I asked management if the firm performs Mock Recalls and Ms. Sharma responded yes. This information was not verified. She told me that the firm performs traceback and trace forward.

## Objectionable Conditions and Management Responses

The following members of management were in attendance during the close-out meeting: Mr. Eric P. Zicher, Director of Food Safety, Ms. Anupam (N.M.I,) Sharma, Food Safety & Quality Manager, and Ms. Mary D. Madison, Quality Regulatory Manager. In addition, we were joined by Mr. Ronald Sammeth, Chief Operating Officer on the telephone. This inspection was classified as NAI. Although, the firm was not

issued an FDA Form 482 at the close of this inspection. The following concerns were discussed in detail with management as follows:

1. I observed light seeping through dock door #5 during the walk-through.
2. I observed that the firm is not consistent with recordkeeping after reviewing training documents.
3. I observed that the consumer complaint investigation for consumer complaint #170623 should have had a faster response.
4. I observed that the firm's pest control activities are inconsistent and needs work.
5. I observed a production employee cleaning equipment located along the north wall adjacent to Production Line (b) (4) with a long white towel using his right hand to touch the floor for balance and alternating the towel in his right hand as he cleans the conveyor equipment on top.

Management Response:

Mr. Zicher promised to make corrections to the observations as soon as possible.

## Refusals

I did encounter one refusal during this inspection which converted to an electronic view of consumer complaint #170623 for closure.

## General Discussion

I requested a copy of the firm's Consumer Complaint Procedure. Instead, I was provided a copy of the firm's Customer Supplied Materials Procedure via email on September 28, 2022. (See Exhibit #6) I reviewed this procedure, and it was not easy to read or understand. N.B.-This procedure revision numbers are incorrect and annual reviews list the same revision numbers although they were reviewed in completely different years. The current revision number should be 12 instead of 6.

| Revision Number | Effective Date | Revision Log | Approved By | Approved Date |
|---|---|---|---|---|
| 4.0 | 9/15/11 | AR/NC | (b) (6) | 9/14/2011 |
| 4.0 = 5.0 | 11/26/12 | AR/NC | | 11/24/12 |
| 4.0 = 6.0 | 02/21/14 | AR/NC | | 2/19/14 |
| 4.1 = 6.1 | 4/07/14 | Changed Procedure | | 4/5/14 |
| 6.0 = 12 | 07/22/21 | Updated | Erich Zicher | 07/16/21 |

*Ledger:* AR = Annual Review; NC = No change

## Additional Information

***Pest Control***

The firm's pest control is monitored by (b) (4) is located at (b) (4). Their telephone number is (b) (4)

The firm is concerned with rodents and insects. The firm's preventive controls consist of (b) (4) traps, (b) (4) and (b) (4) traps. I randomly reviewed the firm's pest control records from January 2022 to August 2022.

The firm's pest control records indicated that there is no consistent follow-up between the firm and the pest control technician after the service is completed. This issue appears to be ongoing for quite some time. I asked Mr. Zicher if the firm has considered replacing this pest control company due to a lack of genuine service capabilities. Mr. Zicher responded that it has been considered.

***Parking/Entry:***

FYI! - The facility's visitor's parking is limited. In addition, the signage for visitor's parking is in an inconspicuous location. It's attached to the entry area façade of the building much higher than normal posting therefore, making it easy to overlook. NB: Prepare to locate available parking anywhere in the firm's parking lot.

The entry area is a virtual set-up. If you are equipped with the Director of Food Safety's cell number, please use it for prompt entry.

***Food Defense:***

The firm's culture regarding Food Defense consists of "see something, say something" per management. In the firm's employee badging and entry area the firm is equipped (b) (4) (b) (4). But the main entry into the building (b) (4) (b) (4). On September 28, 2022, I was allowed entry into the facility without signing in because there were no sign-in sheets available. I was told its okay. On September 29, 2022, the same scenario, I told the escort there were no sign-in

sheets available. This time that individual returned with a sign-in sheet. The firm's business entry is easily accessible due to (b) (4) through the lobby door. Management should be aware and concerned about who enters their facility and their whereabouts upon entry.

### Samples Collected

I did not take any samples and/or photos during this inspection.

### Voluntary Actions

I did not witness any voluntary actions during this inspection.

### Exhibits Collected

1. Organizational Chart
2. Management Training Certs – 3 pages
3. (b) (4) – 2 pages
4. (b) (4) Labels
5. (b) (4) Candy Wrappers
6. Consumer Complaint Procedure (Customer Supplied Materials) – 3 pages

### Attachments

1. FDA Form 482 Notice of Inspection dated September 28, 2022 – 3 pages

10/18/2022

X Clotia C. Abbey-Mensah

Clotia C. Abbey-Mensah

Signed by: Clotia C. Abbey-mensah -S

**United States Food and Drug Administration**

**Consumer Complaint / Injury Report**

**Exhibit 3**

This is an accurate reproduction of the original electronic record as of 03/01/2023

**COMPLAINT # 170623**

| Complaint Date | Receiving Organization | Accomplishing District | How Received | Complaint Source | Complaint Received By | Complaint Status |
|---|---|---|---|---|---|---|
| 10/14/2021 | SEA-DO | CHI-DO | Telephone | Consumer | Muir,Sunny R | In Progress - Pending Evaluation |

**Complainant Identification**

| Name | Address |
|---|---|
| (b) (6) | (b) (6) |

| Phone (W) | Phone (H) | Source POC Name | Source Phone |
|---|---|---|---|
| UKN | (b) (6) | | |

**Complaint/Injury**

| Complaint Description | Adverse Event Result | Adverse Event Date | Injury / Illness |
|---|---|---|---|
| On 10/14/21, a complainant called and alleged her husband had a cough and sore throat after consuming (b) (4) (b) (4) Cheese Flavored Snacks packaged in a 20 oz, 1.4 oz rigid plastic container with screw on lid with a heat sealed film. She stated that in addition to her husband, she consumed the product, as well as, her mother and daughter however, none of these individuals got sick. She indicated her husband did not seek medical attention because he was unsure if the symptoms were due to seasonal allergies or eating the product. The complainant stated she purchased the product from the (b) (4) (b) (4) on 10/13/21. On 10/13/21, she attempted to unscrew the lid, but was not able to. Her husband unscrewed the lid and the complainant stated the plastic film looked as though it had been burnt around the edges and was discolored. The complainant stated the lid also appeared to have a burn mark where the plastic film can into contact with the lid. The four individuals that ate the product stated it tasted like "plastic" The complainant called and reported the complaint to (b) (4) Customer Service.<br><br>On 10/19/21, I spoke to (b) (6), (b) (4) Team Supervisor, (b) (4) who told me she was not aware of any similar complaints regarding the product, but would reach out to the manufacturer who is a co-packer for (b) (4). (b) (6) indicated it was probably due to the heat seal being burnt. (b) (6) contacted me after speaking to the manufacturer, Creative Werks in Bartlett, IL, who told her they had not received any similar complaints and were not aware of any issues. | Non-Life Threatening Injury/Illness - No Adverse Event Reporting | 10/17/21 | Other - identify in Remarks |

| Notify OEO? | Notification Date | Attended Health Professional? | Required Hospitalization? | Emergency Room / Outpatient Visit? | Reported Complaint To? | Need addnl. FDA Contact? |
|---|---|---|---|---|---|---|
| Yes | 10/19/2021 | No | No | No | Reported to Manufacturer | |

**Complaint # 170623**

**Remarks**
Sore throat cough

**Complaint Symptoms**

| Sympton | System Affected | Onset Time | Duration | Remarks |
|---|---|---|---|---|
| Coughing | RESPIRATORY | Hours | Hours | |
| Sore throat | RESPIRATORY | Hours | Hours | |

**Health Care Professional**

| Provider Name | Address | Phone | Occupation |
|---|---|---|---|

**Hospital Information**

| Hospital Name | Address | Phone | Dates of Stay |
|---|---|---|---|

**Emergency Room/Outpatient Visit**

| Hospital Name | Address | Phone | ER Date |
|---|---|---|---|

**Product and Labeling**

| Brand Name | Product Name | Product Code | Product Description | PAC | UPC Code |
|---|---|---|---|---|---|
| (b) (4) | (b) (4) (b) (4) Cheese Flavored Snacks | 07BHT03 | Cheese Puffs, Fired;Nonflex Plastic;Packaged Food (Not Commercially Sterile) | 03R801 | 0284005642 7 |

| Qty / Unit / Package | Lot/ Serial # | Exp/Use by Date | Purchase Date | Product Used | Amount Consumed/Used |
|---|---|---|---|---|---|
| 21.4 Ounces Jar | (b) (4) | 22 FEB 2022 | 10/13/21 | No | 10 |

| Date Used | Date Discontinued | Amount Remained | Imported Product? | Country of Origin | Label Remarks |
|---|---|---|---|---|---|
| 10/13/21 | 10/13/21 | REMAINING CONTAINER | No | United States | Primary panel has red, orange, yellow, and black print, packaged in a plastic container screw top lid with plastic heat sealed film |

**Retail**

**Problem Ingredient Group**

| Name | Address |
|---|---|
| | (b) (4) |

**Manufacturer/Distributor**

| FEI | Name & Address | Home District | Firm Type |
|---|---|---|---|
| (b) (4) | (b) (4) (b) (4) | DAL-DO | Corporate Headquarters |
| 3011417063 | Creative Werks 1350 Munger Rd Bartlett Illinois United States 60103-1698 | CHI-DO | Manufacturer |

**Initial Evaluation/Initial Disposition**

| Problem Keyword | Problem Keyword Details |
|---|---|
| Off-Taste | burnt plastic taste |

| Initial Evaluation | Initial Disposition | Disposition Made By | Disposition Date |
|---|---|---|---|

**Initial Disposition Remarks**

Manufacuter identified by (b) (6), (b) (4) Team Supervisor, (b) (4).

**Referrals**

| Org Name | HHS Mail Code |
|---|---|
| CHI-IB | HFR-MW150 |

**There are no Cosmetics details for this Complaint.**

**There are no Adverse Event details for this Complaint.**

**Related Complaints**

Exhibit 4

## RE: FDA Inspection Routine Inspection - Day 2

---

**From:** Mary Madison mmadison@cwerksglobal.com
**To:** Erich Zicher ezicher@cwerksglobal.com, Anupam Sharma asharma@cwerksglobal.com, Angela Knabe aknabe@cwerksglobal.com, Patrick Woodward pwoodward@cwerksglobal.com, Wendy Proulx wproulx@cwerksglobal.com, Billy King bking@cwerksglobal.com, Teresa Noles-Puccio tnpuccio@cwerksglobal.com, Ronald Sammeth rsammeth@cwerksglobal.com, Steve Schroeder sschroeder@cwerksglobal.com, Jürgen Peters jpeters@cwerksglobal.com, Doug Mauger dmauger@cwerksglobal.com, Gretchen LeMay glemay@cwerksglobal.com, Erik Peterson epeterson@cwerksglobal.com, Ulises Rodela urodela@cwerksglobal.com, Mart Brosas Mbrosas@cwerksglobal.com, Tim Boyd tboyd@cwerksglobal.com
**Cc:** cwerks_salaried_associates cwerks_salaried_associates@cwerksglobal.com
**Sent:** Friday, September 30, 2:53 PM

Good day all,

Attached you will find Regulatory Observations made during the FDA inspection at Bartlett held 9.28-29.2022.

I am hopeful that this will help clarify the asks that were made and the findings noted from the inspection.

If you should have any questions comments or concerns, please feel free to reach out to me at your earliest convenience.

Everyone have an awesome weekend.

[[#]]
Name: Mary Madison
Phone: 773.297.9569
[[#]]

---

**From:** Erich Zicher <ezicher@cwerksglobal.com>
**Sent:** Thursday, September 29, 2022 9:38 PM
**To:** Anupam Sharma <asharma@cwerksglobal.com>; Angela Knabe <aknabe@cwerksglobal.com>; Mary Madison <mmadison@cwerksglobal.com>; Patrick Woodward <pwoodward@cwerksglobal.com>; Wendy Proulx <wproulx@cwerksglobal.com>; Billy King <bking@cwerksglobal.com>; Teresa Noles-Puccio <tnpuccio@cwerksglobal.com>; Ronald Sammeth <rsammeth@cwerksglobal.com>; Steve Schroeder <sschroeder@cwerksglobal.com>; Jürgen Peters <jpeters@cwerksglobal.com>; Doug Mauger <dmauger@cwerksglobal.com>; Gretchen LeMay <glemay@cwerksglobal.com>; Erik Peterson <epeterson@cwerksglobal.com>; Ulises Rodela <urodela@cwerksglobal.com>; Mart Brosas <Mbrosas@cwerksglobal.com>; Tim Boyd <tboyd@cwerksglobal.com>
**Cc:** cwerks_salaried_associates <cwerks_salaried_associates@cwerksglobal.com>
**Subject:** FDA Inspection Routine Inspection - Day 2

Hello Team,

We concluded our FDA inspection earlier this evening. High level summary of today's visit is as follows:

- Inspector arrived at 12:40 PM
- Rereviewed the complaint related to PepsiCo that was discussed yesterday
- Confirmed our refuse hauler information was consistent with Bru
- Review of Pest Control Records
- Review of Sanitary Transit Records

- Review of Food Safety Plan Process Flow Diagrams
- Review of Environmental Monitoring and Water Testing
- Review of Sanitation Processes
- Discussed Label Control
- Tour of Bartlett (Details in Closeout Meeting Observations)
- Inspector Reviewed Details of Packaging Sample Collected
- Inspector Performed Closeout Meeting (Details in Closeout Meeting Observations)
- Inspector concluded at approximately 6:25 PM

**Closeout Meeting**

Attendees:

- Ron Sammeth
- Erich Zicher
- Anu Sharma
- Mary Madison

Feedback: no 483's were issued for the visit. The below were discussion points that the inspector indicated will be included in the report:

1. Doc review: Pest control records demonstrated that our service provider needs to improve upon their communication
2. Doc review: Consistency of manual training records was mentioned pertaining to the printing/signing/dating of recipient names
3. Walk: Dock door #5 had light showing at the base of the door
4. Walk: EE cleaning LN 7300 was witnessed touching the floor and then using same hand to continue cleaning
5. Pepsi Complaint: Concern over lack of urgency in addressing the referenced FDA complaint (complaint received from PepsiCo: 5/28/21, CA completed by CW: 6/7/21, date of FDA referenced complaint: Oct. '21)

I would like to thank the Bartlett Leadership Team for their efforts in supporting this visit. The site

showed extremely well, aside of the two observations noted by the inspector. I would also like to express my appreciation for @Anupam, @Angela, @Mary, @Patrick, @Wendy, @Teresa, @Billy, all whom supported various parts of the inspection and document review. Thanks also for @Ronald in being available for both escalations during the inspection and being able to join in at a moment's notice for the closeout meeting.

Me and my team will be reaching out to clients as required per their respective quality manuals to inform them of the visit. Please let me know should there be any questions.

Best,

creative werks

**Erich Zicher**
Director of Food Safety

1470 Brummel Ave,
Elk Grove Village, IL 60007
+1-630-509-3087 *(office)*
+1-847-826-9424 *(mobile)*
creative-werks.com

Exhibit 5

## Re: [External] FDA Inspection

---

**From:** Cadet, Teddy TCADET@hersheys.com
**To:** Angela Knabe aknabe@cwerksglobal.com
**Cc:** Erich Zicher ezicher@cwerksglobal.com, Mary Madison mmadison@cwerksglobal.com
**Sent:** Thursday, September 29, 5:22 PM



Angie,

That's fine. They are entitled to samples of product packaging during an inspection.

Thanks,
Teddy

Teddy Cadet
Sr. Specialist QRC
The Hershey Company

---

**From:** Angela Knabe <aknabe@cwerksglobal.com>
**Sent:** Thursday, September 29, 2022 6:10 PM
**To:** Cadet, Teddy <TCADET@hersheys.com>
**Cc:** Erich Zicher <ezicher@cwerksglobal.com>; Mary Madison <mmadison@cwerksglobal.com>
**Subject:** [External] FDA Inspection



Hi Teddy –
Bartlett is being inspected by the FDA. They would like to take an EMPTY Hershey cane, however, would be labeled – KitKat.

Any issues with this?

**Angela Knabe**
Quality Regulatory Manager

1470 Brummel Ave,
Elk Grove Village, IL 60007
+1-630-422-3610 *(office)*
+1-262-617-6877 *(mobile)*
creative-werks.com

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19 E Chocolate Ave
Hershey, PA 17033
Mobile 717-412-8517
tcadet@hersheys.com

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**Exhibit 6**

## RE: Nestle

---

**From:** Erich Zicher
ezicher@cwerksglobal.com
**To:** Mary Madison
mmadison@cwerksglobal.com
**Sent:** Thursday, October 13, 4:16 PM

Hi Mary,

Here is what I can glean from the action register:

- Car 3: I really do not want to make any changes here, nor do I feel that it is necessary based upon our finished goods micro results.
- Car 4: Don't see where Angie did this work. If you have a copy send it to me for approval. Otherwise, let me know and I should be able to finish it in around 30 minutes.
- Car 7: I will need to loop in Ron and Javad on this. I can get a meeting scheduled for the end of the month.
- Car 8: Follow up w/ Michaela (should have 385 continuing next week)
- Car 10: Please discuss appropriate materials with Brian and David and make an update to the WI.
- Car 11: I know that you're already working on cleaning up approved suppliers.
- Car 14: Pending response from Donna
- Car 17: Confirm with Matt/Michaela training was completed. I would still like to modify our net contents program, but would like to have Marcus lead and his bandwidth is being sucked up currently.
- Car 19: Did not discuss last trace exercise at Sept. Food Safety Team Meeting… need to discuss tomorrow.
- Car 20/22: Confirm training with Matt/Michaela from Donna
- Car 24: Submitted in July, still not uploaded. Currently shopping other service

providers.

- Car 29: Need to follow up with Jose Lopez – checked but he had left for the day
- Car 30: Repaired – follow up with Jose Lopez for evidence.
- Car 31: Discussed with Michael last week. Do not have further status.

I hope that this is helpful. Please let me know what else you require for support.

Best,

**Erich Zicher**
Director of Food Safety

1470 Brummel Ave,
Elk Grove Village, IL 60007
+1-630-509-3087 *(office)*
+1-847-826-9424 *(mobile)*
creative-werks.com

---

**From:** Mary Madison <mmadison@cwerksglobal.com>
**Sent:** Thursday, October 13, 2022 3:13 PM
**To:** Erich Zicher <ezicher@cwerksglobal.com>
**Subject:** Nestle

Hi Erich,

Donna asked if I could make updates to the CAR tracker. I was wondering did you get a chance to address the CAR request that I emailed you about before.

Please advise.

Thanks a bunch!

**Mary Madison**
Quality Regulatory Manager

1470 Brummel Ave,,
Elk Grove Village, IL 60007
773-297-9569 *(mobile)*
creative-werks.com

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**Exhibit 7**

## RE: BDG Quality Audit

---

**From:** Mary Madison mmadison@cwerksglobal.com
**To:** Sandy Kumar SKumar2@bdgrowers.com, Erich Zicher ezicher@cwerksglobal.com, awilliams@bdgrowers.com awilliams@bdgrowers.com, Jacquelyn LaManna jlamanna@cwerksglobal.com, Angela Knabe aknabe@cwerksglobal.com
**Cc:** Colleen Coyle ccoyle@cwerksglobal.com, Michaela Keslerova MKeslerova@cwerksglobal.com, Keira Dhillon KKaur@bdgrowers.com
**Sent:** Tuesday, October 4, 7:48 AM

Good day

Hope all is well!

Thank you for providing your audit plan. I look forward to meeting with you.

If you need anything please let me know.

Respectfully
[[#]]
Name: Mary Madison
Phone: 773.297.9569
[[#]]

---

**From:** Sandy Kumar <SKumar2@bdgrowers.com>
**Sent:** Monday, October 3, 2022 5:32 PM
**To:** Erich Zicher <ezicher@cwerksglobal.com>; awilliams@bdgrowers.com; Jacquelyn LaManna <jlamanna@cwerksglobal.com>; Angela Knabe <aknabe@cwerksglobal.com>; Mary Madison <mmadison@cwerksglobal.com>
**Cc:** Colleen Coyle <ccoyle@cwerksglobal.com>; Michaela Keslerova <MKeslerova@cwerksglobal.com>; Keira Dhillon <KKaur@bdgrowers.com>
**Subject:** RE: BDG Quality Audit

Hello Creative Werks Team,

The BDG auditor (Keira, copied on this email) will arrive at the below location at 9AM on Thursday 10/6.

222 Sievert Ct.
Bensenville, IL 60106

Please let us know who should be her point of contact at arrival.

Audit agenda is attached.

Thank you,

Sandy Kumar
Global Quality Systems Manager
Blue Diamond Growers
Mobile: 916-695-0074
skumar2@bdgrowers.com

---

**From:** Erich Zicher <ezicher@cwerksglobal.com>
**Sent:** Thursday, September 29, 2022 7:22 AM
**To:** Sandy Kumar <SKumar2@bdgrowers.com>; Alex Williams <awilliams@bdgrowers.com>; Jacquelyn LaManna <jlamanna@cwerksglobal.com>; Angela Knabe <aknabe@cwerksglobal.com>; Mary Madison <mmadison@cwerksglobal.com>
**Cc:** Colleen Coyle <ccoyle@cwerksglobal.com>; Michaela Keslerova <MKeslerova@cwerksglobal.com>
**Subject:** [EXTERNAL] - RE: BDG Quality Audit

Adding @Mary

**Erich Zicher**
Director of Food Safety

1470 Brummel Ave,
Elk Grove Village, IL 60007

creative werks
+1-630-509-3087 *(office)*
+1-847-826-9424 *(mobile)*
creative-werks.com

Complex packaging solutions with speed and peace of mind

---

**From:** Sandy Kumar <SKumar2@bdgrowers.com>
**Sent:** Thursday, September 29, 2022 8:56 AM
**To:** awilliams@bdgrowers.com; Erich Zicher <ezicher@cwerksglobal.com>; Jacquelyn LaManna <jlamanna@cwerksglobal.com>; Angela Knabe <aknabe@cwerksglobal.com>
**Cc:** Colleen Coyle <ccoyle@cwerksglobal.com>; Michaela Keslerova <MKeslerova@cwerksglobal.com>
**Subject:** RE: BDG Quality Audit

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good Morning,

Completed wellness forms are attached. I will send the audit agenda on Monday, 10/3.

Thank you,

Sandy Kumar
Global Quality Systems Manager
Blue Diamond Growers
Mobile: 916-695-0074
skumar2@bdgrowers.com

---

**From:** Alex Williams <awilliams@bdgrowers.com>
**Sent:** Thursday, September 15, 2022 2:18 PM
**To:** Erich Zicher <ezicher@cwerksglobal.com>; Jacquelyn LaManna <jlamanna@cwerksglobal.com>; Angela Knabe <aknabe@cwerksglobal.com>
**Cc:** Sandy Kumar <SKumar2@bdgrowers.com>;

Colleen Coyle <ccoyle@cwerksglobal.com>;
Michaela Keslerova
<MKeslerova@cwerksglobal.com>
**Subject:** RE: BDG Quality Audit

Hi Erich,

Thank you for sending over the information and PDF's. These have been forwarded to the BDG auditors, along with the request for information on any dietary restrictions.

The proposed audit plan will be provided a few days in advance of the audit for your team to review and prepare.

Thank you,

Alex Williams
Co-Manufacturing Category Lead
Blue Diamond Growers
(916) 208-0084

---

**From:** Erich Zicher <ezicher@cwerksglobal.com>
**Sent:** Thursday, September 15, 2022 12:27 PM
**To:** Alex Williams <awilliams@bdgrowers.com>;
Jacquelyn LaManna
<jlamanna@cwerksglobal.com>; Angela Knabe
<aknabe@cwerksglobal.com>
**Cc:** Sandy Kumar <SKumar2@bdgrowers.com>;
Colleen Coyle <ccoyle@cwerksglobal.com>;
Michaela Keslerova
<MKeslerova@cwerksglobal.com>
**Subject:** [EXTERNAL] - RE: BDG Quality Audit

Hi Alex,

Please find attached CW's Vaccination Declaration and Wellness Screening. The facility is located at:

222 Sievert Ct.
Bensenville, IL 60106

Upon arrival to the facility, you should drive counter-clockwise around the building to the office parking lot (there will be marked visitor parking). Enter at Door G, and sign in using the LobbyGuard kiosk. You host (myself) will come a greet you there.

If possible, please provide a proposed audit plan. Should the auditors have any dietary restrictions, you may also send those to us so we can plan accordingly for lunch.

Please let me know should there be any additional questions prior to the audit.

Best,

creative werks

**Erich Zicher**
Director of Food Safety

1470 Brummel Ave,
Elk Grove Village, IL 60007
+1-630-509-3087 *(office)*
+1-847-826-9424 *(mobile)*
creative-werks.com



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**From:** Alex Williams <awilliams@bdgrowers.com>
**Sent:** Thursday, September 15, 2022 2:05 PM
**To:** Jacquelyn LaManna <jlamanna@cwerksglobal.com>; Erich Zicher <ezicher@cwerksglobal.com>; Angela Knabe <aknabe@cwerksglobal.com>
**Cc:** Sandy Kumar <SKumar2@bdgrowers.com>; Colleen Coyle <ccoyle@cwerksglobal.com>; Michaela Keslerova <MKeslerova@cwerksglobal.com>
**Subject:** RE: BDG Quality Audit



Thank you Erich and Jackie.

Who should our auditors contact prior to the audit for any visitor forms (COVID form, GMP, etc.) and information for the visit to the facility?

Thank you,

Alex Williams
Co-Manufacturing Category Lead
Blue Diamond Growers
(916) 208-0084

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**From:** Jacquelyn LaManna <jlamanna@cwerksglobal.com>
**Sent:** Thursday, September 15, 2022 9:45 AM
**To:** Erich Zicher <ezicher@cwerksglobal.com>; Angela Knabe <aknabe@cwerksglobal.com>; Alex Williams <awilliams@bdgrowers.com>
**Cc:** Alex Williams <awilliams@bdgrowers.com>; Sandy Kumar <SKumar2@bdgrowers.com>; Colleen Coyle <ccoyle@cwerksglobal.com>; Michaela Keslerova <MKeslerova@cwerksglobal.com>
**Subject:** [EXTERNAL] - RE: BDG Quality Audit

Thank you for confirming.

@Alex Williams – let me know if you need anything else.

Thanks,

**Jacquelyn LaManna**
Project Manager

1470 Brummel Ave,
Elk Grove Village, IL 60007
+1-630-509-3039 *(office)*
creative-werks.com

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**From:** Erich Zicher <ezicher@cwerksglobal.com>
**Sent:** Thursday, September 15, 2022 11:41 AM
**To:** Jacquelyn LaManna

<jlamanna@cwerksglobal.com>; Angela Knabe <aknabe@cwerksglobal.com>
**Cc:** awilliams@bdgrowers.com; Sandy Kumar <SKumar2@bdgrowers.com>; Colleen Coyle <ccoyle@cwerksglobal.com>; Michaela Keslerova <MKeslerova@cwerksglobal.com>
**Subject:** RE: BDG Quality Audit

Hi Jackie,

We can schedule for 10/6/22.

Thanks,

**Erich Zicher**
Director of Food Safety

1470 Brummel Ave,
Elk Grove Village, IL 60007
+1-630-509-3087 *(office)*
+1-847-826-9424 *(mobile)*
creative-werks.com

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**From:** Jacquelyn LaManna <jlamanna@cwerksglobal.com>
**Sent:** Thursday, September 15, 2022 11:23 AM
**To:** Angela Knabe <aknabe@cwerksglobal.com>; Erich Zicher <ezicher@cwerksglobal.com>
**Cc:** awilliams@bdgrowers.com; Sandy Kumar <SKumar2@bdgrowers.com>; Colleen Coyle <ccoyle@cwerksglobal.com>
**Subject:** BDG Quality Audit

Good morning,

BDG is looking to schedule and audit at our Bensenville location for a 1-day audit on one of the below dates. If there are any questions both Alex and Sandy from BDG are copied on this email.

Wednesday, October 5th
Thursday, October 6th

Thanks,

creative werks

**Jacquelyn LaManna**
Project Manager

1470 Brummel Ave,
Elk Grove Village, IL 60007
+1-630-509-3039 *(office)*

creative-werks.com



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*****Communications may be monitored for quality assurance and security purposes. This correspondence may contain confidential information. Unless you are the addressee (or you are authorized to receive for the addressee), you may not copy, use, or distribute this information. If you have received this in error, please advise the sender immediately at Blue Diamond Growers and permanently delete all copies, electronic or other, you may have.*****

audit deficiencies

told to not address

**Exhibit 8**

## Blue Diamond Audit

**From:** Mary Madison
mmadison@cwerksglobal.com
**To:** Erich Zicher ezicher@cwerksglobal.com,
Angela Knabe aknabe@cwerksglobal.com
**Sent:** Wednesday, October 5, 7:27 AM

Good day,

Hope your day is getting off to a great start.

In preparing for the audit several policies were deficient/incomplete. What is the protocol used or what is the best approach to this situation?

Thanking you in advance for your assistance.

Warm Regards

[[#]]
Name: Mary Madison
Phone: 773.297.9569
[[#]]

**Exhibit 9**

<SKumar2@bdgrowers.com>; Michael Kettelman <mkettelman@bdgrowers.com>; Anthony Melo <AMelo@bdgrowers.com>; Steven Phillips <SPhillips@bdgrowers.com>
**Subject:** RE: Creative Werks Audit Report 10.6.2022 BDG audit

Good day Ms. Dhillon,

Hope you are having an outstanding day thus far!

It was indeed a pleasure to meet you as well. I appreciate your time and attention to detail during the audit. Further, I appreciate your kind words and the proactivity in narrowing down the scope of the audit.

I hope you had a safe trip home.

We are currently working on the outstanding issues and will meet the targeted deadline for compliance.

Thank you again.

Kindest regards,
[[#]]
Name: Mary Madison
Phone: 773.297.9569
[[#]]

**From:** Keira Dhillon <KKaur@bdgrowers.com>
**Sent:** Monday, October 10, 2022 3:25 PM
**To:** Mary Madison <mmadison@cwerksglobal.com>; Erich Zicher <ezicher@cwerksglobal.com>; Michaela Keslerova <MKeslerova@cwerksglobal.com>; Colleen Coyle <ccoyle@cwerksglobal.com>; Angela Knabe <aknabe@cwerksglobal.com>; Jacquelyn LaManna <jlamanna@cwerksglobal.com>
**Cc:** awilliams@bdgrowers.com; Sandy Kumar <SKumar2@bdgrowers.com>; Michael Kettelman <mkettelman@bdgrowers.com>; Anthony Melo <AMelo@bdgrowers.com>; Steven Phillips <SPhillips@bdgrowers.com>

Creative Werks Team,

It was an absolute pleasure meeting you all during recent audit visit. Please find attached the audit report with two minor Non-Conformances.
You have 30 days from today, to address these NC's.

Below are some of the highlights from the audit.

- An outstanding well-organized audit, whole team exhibited audit readiness. The documents, records, and any other information requested was readily available.
- The owners of the programs, policies, and records were always present in the conference room during the audit to facilitate the steady flow.
- Employee Interviews, CCP checks- Performed successfully.
- Very clean and organized facility.
- Overall, the audit scored "Excellent"

Again, thank you all and keep up the good work!

Please feel free to reach out to myself or Sandy Kumar if you have any questions.

Best,

Keira Kaur Dhillon
Corporate Manager, Quality Assurance
kkaur@bdgrowers.com |Office: 916.446.8636
**Blue Diamond Growers** | 1802 C Street |Sacramento CA 95811 |

NESTLE Prerequisite – more (design) gap

| SECTION | REQUIREMENT | AUDITOR FINDINGS | RATING | AUDITOR NOTES | CAR # | CORRECTIVE ACTIONS | PERSON RESPONSIBLE | ESTIMATED DATE (See Comment) | STATUS | CONFIRMED BY WHO, WHAT | 2022-09-30 NOTES |
|---|---|---|---|---|---|---|---|---|---|---|---|
| HACCP | All Nestlé products and their components, including raw materials, packaging materials and process aids, are considered in a HACCP study. All processing steps and movement are considered in the HACCP study. | The Ingredient Risk Assessment document lists potential hazards for high-level ingredient/WIP groups (e.g. chocolate with inclusions, chocolate, or nuts) however no risk assessment (evaluating severity / likelihood) is performed. Risk Assessment documented conclusion (See Auditor Notes) does not negate the site's responsibility to evaluate the risks of the site's incoming materials.<br><br>The current grouping of ingredients will not adequately support a proper risk assessment of incoming materials<br><br>Same finding for packaging and process. | Major | One Food Safety Plan for packaging (across all three factories), one for coffee, one for Tubes and Toppers<br><br>Documented conclusion reached on ingredient hazards in the Ingredient Risk Assessment states, "Client... have instituted policies around Biological and Chemical concerns with their food manufacturers which we verify through our Auto hold / CofA process" | 1 | Food safety plans will be re-written to included severity and likelihood.<br>Food safety plans will be re-drafted to include the hazard analysis within - not as a separate document. Packaging and process will also be included. | Angie | 1-Nov-22 | | | 117.126 (SSP)<br>(b) – 117.130 (a)(2)<br>– 117.135(b)<br>– Subpart G-as Subpart C<br>– 117.139(a)<br>– 117.145(a)(1)<br>– 117.150(a)<br>– 117.165(b)<br>(c) Records |
| HACCP | An annual review of the HACCP study must take place and all updates must be captured. | Ingredient Risk Assessment changes are not included in the annual reviewed and no change control associated | Major | 11/4/21 Pkg Food Safety Plan | 2 | Since the risk assessment will be embedded within the food safety plan, it will become part of the annual review. New change control froms will include a review of the food safety plan for new processes or products. | Angie | 1-Nov-22 | | | |
| Microbiology | The relevant pathogen(s) as well as the associated hygiene indicator(s) has been identified. | Relevant hygiene indicators are not be being tested (e.g. Eb for Salmonella) | Minor | Target organisms are Listeria spp and Salmonella; Currently uses hygiene indicators only to show effectiveness of cleaning (validations) | 3 | Will review the program and how best to address | Erich | 1-Oct-22 | | | |

Preventive Control

Take screen shots if not working

July 2022

Mandatory Documents
- Quality SOC
- forms
- Packet

Chapter 1-4

Chapter 5.
Unique → Criteria

A central form
Certificate of destruction

Archive - Staff time to make

MAD
Mayr Alley Dec

| SECTION | REQUIREMENT | AUDITOR FINDINGS | RATING | AUDITOR NOTES | CAR # | CORRECTIVE ACTIONS | PERSON RESPONSIBLE | ESTIMATED DATE *(See Comment)* | STATUS | CONFIRMED BY WHO, WHAT | 2022-09-30 NOTES |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Microbiology | The site Hygienic Zoning program was developed using a risk based analysis. | Sanitation Rooms miscategorized as BGMPs in some documents | Minor | Facility Zoning & Workflow WI-3.1 v10 - dated 2022-01-31 splits facility into 3 zones (non-mfg, BGMPs (all GMPs/partial attire), and PPCA (all GMPs/attire)) Developed based on risk - production environments and the traffic flows around that; Certain areas forktrucks are not allowed due to allergen risks, for example BEN uses Sterliex for forktruck wheels | 4 | Identifying colors will need to be updated to correctly reflect the zoning. | Angie | 11/1/22 15-Sep-22 | | | Revised documents are in routing for approval |
| Microbiology | The site zoning plan must be supported by verification plan with defined verification activities. | The site zoning plan does not appear to be supported by verification plan with defined verification activities. (WI 3.1 also requires annual verification) | Minor | Facility Zoning & Workflow WI-3.1 v10 - dated 2022-01-31 requires Annual Verification in conjunction with the Pkg FS Plan review | 5 | WI does require annual verification - will need to update to define what those verification activities are . | Angie/Erich | 15-Jan-22 | | | |
| Allergen Management | A MAD form or equivalent local document is available for Nestle raw materials and finished products. | A sample review of the Nestlé Finished Product MAD forms (when compared against the site's ERP system) shows some inconsistencies indicating some MAD forms are incorrect. (e.g. M&M Peppermint Hot Cocoa, milk morsel both pack configurations) Nestlé gap: MAD form for incoming material (NTH White Morsel) is out of date) | Minor | MAD forms exist for all active finished good SKUs (confirmed updated within last 3 years) MAD for M&M Peppermint Hot Cocoa indicates treenut as allergen in product (highly refined coconut) - but not in ERP setup / labeled on packaging (suspect error) (also not listed in the different ingredients' MAD) NTH White morsel MAD is out of date (Bloomington source) | 6 | •M&M Peppermint Hot Cocoa – bag has allergens listed as milk & soy, however MAD form dated 3/30/21 (attached) indicates treenut allergen coming from highly refined coconut oil. Coconut oil is not listed on the ingredient statement. oCW team (by 9/16) – review the MAD form for accuracy and advise if update is needed / where coconut oil comes from •NTH Premier White Morsel (ingredient) – MAD and Kosher documentation are from obsolete supplier site (Nestle Bloomington) oSusan (by 9/16) – get updated documentation from current supplier site (Nestle Burlington) | CW Susan CW CW Susan | 9/16 9/16 10/1 10/1 11/1 | Closed | D. Bjurlin - 2022-09-30 - Review of submitted evidence | MAD forms updated and sent; Change control issued with new Incoming Material MAD form. CAR Closed |

| SECTION | REQUIREMENT | AUDITOR FINDINGS | RATING | AUDITOR NOTES | CAR # | CORRECTIVE ACTIONS | PERSON RESPONSIBLE | ESTIMATED DATE *(See Comment)* | STATUS | CONFIRMED BY WHO, WHAT | 2022-09-30 NOTES |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Allergen Management | Is there an Allergen matrix in place | No allergen matrix by line available to provide clarity to all involved which lines may run which allergens (based on cleaning validations/verifications, risk assessment, etc).<br><br>Currently if a change to a line is made, only quality is aware and it on the Quality personnel to attend every Scheduling meetings to prevent Scheduling from selecting a line that is not current on cleaning validations/verifications or allowed to run that allergen at the moment. (See Auditor Notes for additional context) | Major | Changeover matrix available that specifies all allergens from/to and sanitation requirements. Not product specific info. ERP setups specify the full allergen profile of each item being running.<br><br>Reviewed SPC1 Line Clearance & Full sanitation Cleaning Checklist after completing NTH Kitchen Sink product (dairy/soy/wheat) to soy/wheat product from Apr'22. Allergen cleaning - full was completed and verified.<br><br>There is a software that runs a report showing the allergens ran on a line based on the timeline entered. On the line (Ln 380) reviewed, we found that if we looked back to 2021, peanut was listed and when we selected today's date, it is not listed. The line is past due for allergen cleaning verifications. It was stated that they are not allowed to run peanut on the line currently, however when the QAM asked Scheduling of this | 7 | Matrix will be developed detailing which allergens/clients are approved to run on each of the production lines | Angie | 12/31/2022 - realizing this timeline does not meet the deadline for a Major however, this will restructure how we plan and execute production. More time will be required. | | | Work in progress with IT on how to systemically close |

preventive control

Pair weight + Each Run

① Each day tare recorded → (log)

② Sop is different (dud )

| SECTION | REQUIREMENT | AUDITOR FINDINGS | RATING | AUDITOR NOTES | CAR # | CORRECTIVE ACTIONS | PERSON RESPONSIBLE | ESTIMATED DATE *(See Comment)* | STATUS | CONFIRMED BY WHO, WHAT | 2022-09-30 NOTES |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Allergen Management | Are annual verifications in place? | (Repeat finding) Bensenville could not produce evidence of annual verifications on Ln 380 (and there is no control method to prevent scheduling from running peanut on the line as mentioned above) | Major | BRU - Allergen annual verification on Ln1300 performed 4/18/22, Ln 2400 performed 5/2/22; BEN - the evidence could not initially be located and the QA personnel were on vacation - evidence was found for Ln 200 - 3/31/22; Ln 250 - 8/6 & 8/20/21; Ln 380 - 5/21/21 was the last one performed; See above auditor notes for more context | 8 | Will audit to determine why we are behind in validations at Ben. Michaela to propose action plan based on schedule. | follow up c Michaela Angie/Michaela | 1-Oct-22 | | | Ln 250 annual verification - please send the full CW paperwork for the verification believed to be recently performed; Work in progress IT on how to systemi se; |
| Cleaning & Sanitation | Sanitation activities are aligned with MSS (frequency and methodology) | Newly managed in M+; It was discussed that a Scorecard/Dashboard like the Maintenance Work Order system has would be ideal to manage / trend execution | Continuous Improvement | Handled in M+Lightening as a Housekeeping PM; No overdue | 8 | | | | | | |
| FM Control | • Equipment under repair/re-construction/maintenance must be inspected, relating to FB, before being cleared for release. | No evidence could be provided to demonstrate equipment under repair/re-construction/maintenance is inspected (relating to FB or micro) before being cleared for release | Minor | assessing as minor due no processing equipment, the # of FM complaints received, and the overall condition of the facility | 9 | Need to meet with Maintenance and Sanitation to understand the worfklow for items needing maintenance and how those items are then cleared for use in production. | Brian Phillips/Michael Glowa/Angie | 1-Jan-23 | | | Please define FB/FM |
| FM Control | Temporary repairs using inappropriate auxiliary materials such as tape, must be avoided. If temporary repairs are used, there must be a policy which includes finite period of time allowed with proper repair scheduled. | There is no mention of an allowed period of time for proper repairs to be scheduled for temporary repairs. | Minor | Generally not allowed unless waiting on a part, etc, however this was a verbal expectation | 10 | WI for temporary repairs will be updated with the time and materials allowed for temporary repairs | Angie | 1-Oct-22 | | | Maintenance Operating Procedure 5.8 |
| Supplier | Is there logic in place for determining risk of supplier (high versus low)? | Recommend enhancing program to include the HARPC-required risk evaluation for the food ingredient in question to further strengthen the program (currently a peanut supplier has the same risk level as a sugar candy supplier or a coffee supplier) | Continuous Improvement | High Risk Suppliers = Food ingredient or packaging with food contact or nutritional label; High Risk require Supplier Approval; Medium risk may (service based) | 10 | | | | | | HARPC 11/7/126 |

| SECTION | REQUIREMENT | AUDITOR FINDINGS | RATING | AUDITOR NOTES | CAR # | CORRECTIVE ACTIONS | PERSON RESPONSIBLE | ESTIMATED DATE *(See Comment)* | STATUS | CONFIRMED BY WHO, WHAT | 2022-09-30 NOTES |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Raw, Pack & Finished Prod | Materials received from unapproved vendors trigger the exception management process and documented | In general, approving release for incoming materials from unapproved vendors currently does not include involving Nestlé.<br><br>Additionally, during a spot check, an example of (Funfetti) film on auto hold was found to come from American Packaging in Des Moines IA, however, the approved supplier (in Ch 5) is Story City, IA. It did not trigger the ER process and was released internally. (We didn't continue to spot check) | Minor | Since it is the Ship From site that triggers the ERP system to auto-hold, it takes extra manual confirmation by Angie to review if the receipt is from a truly unapproved vendor site or not; We reviewed some examples; Typically the issue is the ship from site is a warehouse, and we can see on the paperwork that the manufacturing location is truly the approved site; We aligned that if this wasn't the case, an ER submitted to Nestle would be required for release moving forward.<br><br>Is there a strong enough tie between the Approved Supplier list in Chapter 5 and the Supplier approval process at CW? | 11 | Approved cw vendors for Nestle will be verified against the list of approved vendors in Chapter 5. If the shipping paperwork identifies a location other than what is on the approved list, an ER will be submitted to Nestle. | Angie | 11.30.22<br>1-Oct-22 | | | |
| Raw, Pack & Finished Prod | Information to support the release decision such as sampling, inspection and analytical data must be recorded and traceable by factories. | Incoming receipt COA review is not consistently requiring the full list of required parameters per the Ch 5 specification or the COA comparison table, when available).<br>Example: 6/2/22 Dulce de Leche truffle receipt COA was missing 3 of the 6 micro parameters listed in the spec (included: Eb, S, TPC; missing: YAM, coliforms, and E.coli) (no further spot check performed)<br><br>The check of the Seal # matching the BOL is not documented. | Major | | 12 | Will review chapter to 5 to determine the micro parameters and then follow up with our suppliers to ensure they are conducting the required tests. Any push back from the suppliers will be escalated to Nestle Quality | Angie | 11.30.22<br>1-Nov-22 | | | |

Preventive Control (PRP)

| SECTION | REQUIREMENT | AUDITOR FINDINGS | RATING | AUDITOR NOTES | CAR # | CORRECTIVE ACTIONS | PERSON RESPONSIBLE | ESTIMATED DATE *(See Comment)* | STATUS | CONFIRMED BY WHO, WHAT | 2022-09-30 NOTES |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Raw, Pack & Finished Prod | The factory is responsible for identifying the release characteristics through the Factory QMS or equivalent. They correspond to:<br>a. Critical Control Points (CCP);<br>b. Operational Pre-Requisite Programs (OPRP);<br>c. Control Points (CP);<br>d. Monitoring inspections (M1) covering contaminants & regulatory requirements (not measured on each batch). | The site's release characteristics are not 100% aligned with the pQMS and/or MI's (Manufacturing Instructions) listed in Chapter 5 (ex: M&M pQMS with regard of level of criticality) | Major | Qwerks is where release characteristics are listed; The FSP is where the SPC and PCPs are denoted<br>Manny Records | 13 | Need to review the pQMS to ensure they align with the information contained within the MIs. Once that has been confirmed as aligning, the information in the Mis needs to align with the release criteria listed in Qwerks. | Amanda/Matt/Michaela | 11.20.22<br>1-Nov-22 | | | Communicate Plan<br>Action Items |
| Raw, Pack & Finished Prod | The use of rework is defined by Nestle Technical Applications. Rework is traced and accounted for. | (Nestlé Gap) The use of rework is not defined in Chapter 5 | Minor | WI 3.10 Rework requires for multi component that they either separate out the individual components and rework or use a separate scale and manage it to where the ratios are still met. Rework has to be done on the same shift, unless the rework is a result of a hold. | 14 | CAR#14: I recall the gap identified here around re-processing, not full fledged rework where a new batch# is assigned. Can you confirm? (Maybe question is to @Bjurlin,Donna,US-Solon) If that's the case proposed action:<br>•CW team (by 10/1) – advise if rework (with new batch # assigned) is a process @ CW, and of so share<br>•CW team (by 10/1) – share any policies around online re-processing<br>•Susan (by 11/1) – Draft rework & re-processing requirements from Nestle with alignment from TAG for current portfolio. | CW<br>CW<br>Susan | 10/1<br>10/1<br>11/1 | | | Rework procedure has been sent. Next steps are in SE's hands |

| SECTION | REQUIREMENT | AUDITOR FINDINGS | RATING | AUDITOR NOTES | CAR # | CORRECTIVE ACTIONS | PERSON RESPONSIBLE | ESTIMATED DATE *(See Comment)* | STATUS | CONFIRMED BY WHO, WHAT | 2022-09-30 NOTES |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Raw, Pack & Finished Prod | Release must be done by:<br>a. The Contract Manufacturer according to mutually agreed standards and rules with Nestlé operating companies, or<br>b. Performed by the Nestlé operating companies | Finished product testing / release is not aligned with the criteria listed in the Chapter 5 (examples found: M&M ratios OOS from 6/23 and released, missing end of runs checks in general, line clearance documentation review is not part of release process | Major | Unapproved vendor finding will be addressed in the finding above and not-double dipped here<br><br>(Line clearance review done earlier in process by other personnel, however there should be some connection that the paperwork is available and complete. | 15 | Will need to review QMS release parameters with the Food Safety and Quality Managers for each site. Will need to determine if another review of the line clearance sheet needs to be apart of the release process. | Quality Management | 1-Nov-22 | | | Talk to angela/eric |
| Raw, Pack & Finished Prod | The information supporting the release decision must be kept during:<br>a. the normal product shelf life;<br>b. certification requirements; or<br>c. the legal retention period.<br><br>Note: Records must be maintained for the longest required period. | Since all docs are kept electronically now and not on hard copy, suggest updating SOP and confirming with IT the lifespan for docs per application to avoid surprises and have an SOP that aligns with current processes. (No gap; just improvement opp) | Continuous Improvement | Docs are stored for 7 years per Doc Control SOP<br>Angie states everything is electronically and kept indefinitely | 15 | | | | | | |
| Net Contents | Product intended for US only: Average Net Content – The lot Average of packed goods (Mo) have been verified to be equal to or higher than the Declared Net Content (E). | Double check proper documentation of production details in the Nestlé lot tool. We found an example from the 6/7/22 run of Dulce de Leche where the Lot tracking tool was dated 5/5/22 on the form incorrectly. | Continuous Improvement | | 15 | | | | | | |
| Net Contents | Product intended for US only: 50% or more of individual packages must be greater than declared label net contents (E) as statistically calculated | The Net Content Compliance WI WI-2.18 does not align with this requirement. The WI states "no more than 30% of the actual samples can fall between Label and MAV" Mathematically, this does not guarantee 50% statistically calculated. | Minor | | 16 | Review of Net Contents WI and practices to ensure the mean value of the population is greater than the declared label weight. Adjustments to WI will be made based upon assessment. | Marcus Willamson | 1-Feb-22 | | | |

| SECTION | REQUIREMENT | AUDITOR FINDINGS | RATING | AUDITOR NOTES | CAR # | CORRECTIVE ACTIONS | PERSON RESPONSIBLE | ESTIMATED DATE *(See Comment)* | STATUS | CONFIRMED BY WHO, WHAT | 2022-09-30 NOTES |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Net Contents | Product intended for US only: With Checkweigher, no packed units below an absolute lower limit - No packed units below an absolute limit (MAV).<br><br>Note (not auditable):<br>Refer to US tab in R3.16.3 Lot Review Selectable Limits<br>USDA MAV Table 2-9<br>FDA labelled by weight MAV Table 2-5<br>FDA labeled by count Table 2-7<br>FDA labeled by liquid or dry volume table 2-6 | Found evidence of a production run with MAVs that was being released by site.<br>(Found hold product due to MAVs during factory walkthrough. Internal notes stated "Pallet would be released as the entire lot met spec". No one from Nestle had been informed - M&M, Production date - 7/20/22) | Minor | MAV samples created and ran across checkweigher bihourly 3 times; | 17 | If finished good failed to meet MAV, this would follow an escalation and ER process which would include Donna to align on next steps. | Matt/Michaela | 15-Sep-22 | | | following matt/ Michaela |
| Net Contents | Product intended for US only: The actual number of units sampled meets the requirements for the legislative sample size in NIST HB 133 Category A Table 2-1. | When the minimum # of samples is not obtained per the Nestlé Lot Tool, there should be documentation to show a review was initiated and the minimum requirement per the NIST HB 133 was obtained for the short run. (Found an example where the Lot Tool stated more samples required and the product was released. Took digging to discern it was a short run and the min was taken. | Continuous Improvement | | 17 | | | | | | |
| Net Contents | Product intended for US only: The tare is determined at the beginning of every production is recorded and used for all scale tares. | Tare is not recorded.<br><br>Tare Variability Study for all products could not be produced per the Net Content Compliance WI WI-2.18, section 5.3.1 | Minor | Spot check: the Morsels & More Tare Variability study could not be located | 18 | Will audit current cw projects running for Nestle to ensure a tare variability study has been conducted and is on file | Matt/Michaela | 15-Feb-23 | | | Please make sure to address the requirement of tare being recorded at the start of each run as well. |
| Traceability | Shelf life extension is:<br>a. Not allowed for raw materials and must be blocked and properly disposed<br>b. Is allowed for packaging materials upon authorization by NPTC/Application Group/Packaging expert. SLED extension can only be done before the original expiry date of packaging materials. | Update WSL reports to include packaging materials and to include CSL (Consumer SLED) | Continuous Improvement | No SLED SOP so falls under Non Conforming Goods Procedure, Supply Chain has enhanced their processes recently to manage soon-to-expire based on MWSL. | 18 | | | | | | |

| SECTION | REQUIREMENT | AUDITOR FINDINGS | RATING | AUDITOR NOTES | CAR # | CORRECTIVE ACTIONS | PERSON RESPONSIBLE | ESTIMATED DATE *(See Comment)* | STATUS | CONFIRMED BY WHO, WHAT | 2022-09-30 NOTES |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Recall & Withdrawa | An after-action review must be conducted when the crisis is over and potential improvements implemented.<br><br>As a minimum, an analysis of the involved quantities of finished products must be made (produced, sold, returned, destroyed and not accounted for or consumed). | After action review not conducted | Minor | Analysis of quantities accounted for | 19 | Results of any mock trace or mock recall will be included in the next month's Food Safety team meeting. | Angie | 13-Sep-22 | | | updated notes to include AAR and will be sending notes over to me soon |
| Control Nonconform & Change Mgmt | Assess if the deviation leads to material rejection (or if the blocked batches may be exceptionally released or unblocked). Release decision is owned by Nestle Quality. | Release decision for non-conformities is not consistently being brought to Nestlé Quality to own | Major | Discovered two situations where product was held and released by Creative Werks in July without communication to Nestlé. Both were for net content.<br>Other spot check - reviewed peanuts that just went on expiry and were on hold pending review | 20 | Any Nestle product that is put on hold will be communicated to Nestle Quality to align with disposition. Training from Matt and Michaela to follow. | Matt/Michaela | 26-Sep-22 | | | DB discussed needs (and the why behind) with Michaela / Matthew in August; Recent hold was communicated to Nestlé, including request for release;<br>Angie/Mary to confirm procedure has expectation stated in it and then we can close car |
| Control Nonconform & Change Mgmt | Check if the same material and/or material batch is (or has been) used in other products and assess the impact accordingly. | Checking to see if the same material and/or material batch is (or has been) used in other products when there is a hold is not documented in the procedure. | Minor | Trace - would run a raw material report to review where used. If any product produced with sublot - automatically put on hold, but if shipped out already - would notify customers. All additional inventory would go on hold. | 21 | Will update procedure to clearly identify what happens then material from a certain lot goes on hold. | Angie | 1-Dec-22 | | | Can you clarify the intent of this corrective action? I am not sure I completely follow. |

| SECTION | REQUIREMENT | AUDITOR FINDINGS | RATING | AUDITOR NOTES | CAR # | CORRECTIVE ACTIONS | PERSON RESPONSIBLE | ESTIMATED DATE *(See Comment)* | STATUS | CONFIRMED BY WHO, WHAT | 2022-09-30 NOTES |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Non Conform & Change Mgmt | Each result which is out of the Factory QMS or equivalent limit(s) for a release characteristic must trigger a Root Cause Analysis (RCA) investigation that leads to corrective action(s) avoiding the re-occurrence of the failed result. | Could not provide evidence of consistent root cause / corrective action on all Nestlé product holds consistent with WI and this Nestlé requirement. | Minor | WI-2.7 Corrective Action / Preventative Actions (CAPA) Rev 7, dated 4/17/20<br>Verbal answer - Per client request will conduct RCA & CAPA. Have internal CAPAs based on trending gap data. No recent CAPAs completed on Nestle items.<br>WI is more black/white on when it is needed vs per client request | 22 | As part of communicating with Nestle on all holds to align on dispositon, it should be communicated whether Nestle will reuqire an RCA and CAPA on the specific hold. | Matt/Michaela | 26-Sep-22 | | | Every hold will require RCA/corrective action. Please adjust corrective action plans accordingly. |
| Non Conform & Change Mgmt | The Contract Manufacturer must have a Management of Change process in place to manage changes to products, processes, equipment & workplaces that affect HACCP program, product quality, food safety, regulatory compliance, (e.g.: change on the label). | Insufficient/ineffective MOC process in place.<br><br>Site could not provide evidence of MOC execution for internally-initiated changes, nor could show proper execution of client-initiated changes. | Major | Examples:<br>M&M ingredient extension MOC dated 1/3/22<br>NTH Generic Release Instructions 6/29/22,<br><br>Change in graphics/item formulation gets communicated from client services email and triggers a review. Would get reviewed due to the primary packaging review to assess any allergen updates needed based on change; Unclear how this ties into the change control process.<br><br>Ingredients - reviewed a FST meeting minutes 7/13/22 where it showed a list of new materials | 23 | Management of Change program will be rewritten to include a new change control form. | Erich/Angie | 15-Oct-22 | | | Please include as part of the corrective action the following:<br>(1) review of the change controls initiated by Nestlé since January 2022 to ensure execution, (2) proper execution in house of future change control beyond SOP / form modification |

| SECTION | REQUIREMENT | AUDITOR FINDINGS | RATING | AUDITOR NOTES | CAR # | CORRECTIVE ACTIONS | PERSON RESPONSIBLE | ESTIMATED DATE *(See Comment)* | STATUS | CONFIRMED BY WHO, WHAT | 2022-09-30 NOTES |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Disposal & Destructio n | Salvage and donations are reviewed and approved by Nestle Quality in advance of any action. | Verbally indicated that donations require client approval, but not documented in policy. | Continuous Improvement | Client approval is required before any donations. No occurrences with NTH product. Salvage/shelf life expiration is managed against Mis, client is notified for shelf life extension requests. Expiring materials are reviewed, and expired materials go on HOLD as a non-confirming material. | 23 | | | | | | |
| Pest Management | Pest Contractor visit reports | Implement routine and KPI to review observations and drive resolution of recommendations in food safety team cadence. | Continuous Improvement | Weekly service visits, 3 reports reviewed from June-July'22. Reports are reviewed with quality team member after each site (both parties sign for acknowledgment) | 23 | | | | | | |
| Pest Management | The frequency and scope of pest monitoring must ensure that new pest activity or increasing trends are detected as early as possible<br><br>Note:<br>The order of priority for preventing and managing pest infestations must follow the sequence below:<br>1. Exclusion of pests from accessing manufacturing buildings, through effective physical or alternate barriers.<br>2. Restriction – denial of food and water to pests that have got into grounds or buildings, through proper storage practices.<br>3.Control – removal of safe harborage in grounds or building fabric and removal of infested material from grounds or establishment | Integrate trending into food safety team monthly meetings for visibility and to address trends where analysis or activity are needed. | Continuous Improvement | Trends are accessible through the website for reporting. Rentokill team attends quarterly quality assessments @ CW.<br><br>Trending to be brought into the food safety team reviews where value added - starting monthly with ambition to reduce to quarterly | 23 | | | | | | |

| SECTION | REQUIREMENT | AUDITOR FINDINGS | RATING | AUDITOR NOTES | CAR # | CORRECTIVE ACTIONS | PERSON RESPONSIBLE | ESTIMATED DATE *(See Comment)* | STATUS | CONFIRMED BY WHO, WHAT | 2022-09-30 NOTES |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Pest Management | Nestle approved pesticide list is available and communicated to the Site IPM Champions and to the pest contractors | No letter of conformance available from Rentokill acknowledging receipt and adherence to the Nestlé approved Pesticide list | Minor | CW team has shared the current approved pesticide list with Rentokill for review, but verification has not yet been completed. List of Rentokill pesticides used is available in portal | 24 | Need to confirm Rentokil has uploaded the most current version of the APL. | Angie | 15-Sep-22 | | | |
| GMP | A preventative maintenance program is in place for all process equipment that includes record-keeping and verification that work is completed. Maintenance request which impact Product Safety are given priority and on a timeline. | It was not evident during the audit that that Maintenance requests that impact Product Safety are given priority and on a timeline. | Minor | PMs are created when equipment comes in the building; PMs are assigned in ManagerPlus (M Plus); Oldest overdue is from 7/2/22, so appears the sites are staying up on PMs well overall; Run PM completion report weekly; Maintenance work requests are prioritized based on the priority of the line at the time; | 25 | Severity of repair has been identified in a Departmental Practice for the maintenance departments. Will need to update document to include an appropriate timeframe for each of the categories (Minor, Normal, Major, Critical) | Brian Phillips | 1-Feb-22 | | | |
| GMP | A program for managing temporary repairs is documented and in place. | The allowable method (vs not allowable) of temporary repairs are not documented | Continuous Improvement | WI 4-5 Maintenance operating Procedure - temp repair not allowed typically; done in food safe way, etc. It was shared for example that no tape or cardboard is allowed and no signs of this observed | 25 | | | | | | |
| GMP | Following major maintenance, work areas are inspected and released for production, with sign-off by the individuals responsible for the inspection. | At the time of the audit, the site could not provide evidence that following major maintenance, work areas are inspected and released for production, with sign-off by the individuals responsible for the inspection (neither in the way of written (or unwritten) procedure nor documented evidence) | Minor | In the workorder system, the maintenance staff will denote a food contact surface was handled and that will send an email notification to QA; It is unclear what happens after the receipt of that email, even by QA; The work order does not have a check box to denote the line has been released back to production.<br><br>assessing as minor due no processing equipment, the # of FM complaints received, and the overall condition of the facility | 26 | Need to meet with Maintenance and Sanitation to understand the worfklow for items needing maintenance and how those items are then cleared for use in production. | Brian Phillips/Michael Glowa/Angie | 1-Jan-23 | | | |

| SECTION | REQUIREMENT | AUDITOR FINDINGS | RATING | AUDITOR NOTES | CAR # | CORRECTIVE ACTIONS | PERSON RESPONSIBLE | ESTIMATED DATE *(See Comment)* | STATUS | CONFIRMED BY WHO, WHAT | 2022-09-30 NOTES |
|---|---|---|---|---|---|---|---|---|---|---|---|
| GMP | Product containers are not used for other purposes. | Suggest this be added to the site GMP policy | Continuous Improvement | Training require product containers are not to be used for any other purposes | 26 | | | | | | |
| Management Commitment | Does the site have a quality policy in place that outlines expectations? | While not an audit requirement, several SOPs (including the Quality Policy) are not in compliance with the site's Document Control SOP requiring annual review | Continuous Improvement | Examples of WI's found to be past the internally required annual review:<br>Raw Material and Finished Good Release WI-2.20 v17.3 - 2019-07-15<br>WI-2.25 Sensory Training v6.0 - 2021-05-27<br>QP-2.0 - Rev 10.2 - 2021-09-23 - not updated annually per Document Control policy<br>Quality policy QP-2.0 - Rev 10.2 - 2021-09-23<br>WI-2.7 Corrective Action / Preventative Actions (CAPA) Rev 7, dated 4/17/20<br>WI-2.9 Change Control Management v9.0 - dated 2020-09-08<br>WI-2.13 - V12.2 - 2021-07-13 | 26 | | | | | | |
| SECTION | LOCATION IN FACTORY | AUDITOR FINDINGS | RISK | AUDITOR NOTES | | | | | | | |

| SECTION | REQUIREMENT | AUDITOR FINDINGS | RATING | AUDITOR NOTES | CAR # | CORRECTIVE ACTIONS | PERSON RESPONSIBLE | ESTIMATED DATE *(See Comment)* | STATUS | CONFIRMED BY WHO, WHAT | 2022-09-30 NOTES |
|---|---|---|---|---|---|---|---|---|---|---|---|
| GMP Inspection | BEN & BAR - Warehouse | REPEAT FINDING: Insufficient programs in place to ensure dock doors and the use of said dock doors do not pose quality / food safety risks.<br>Examples:<br>BAR: 9+ dock door seals (drop curtains, wear pleats, etc) are in disrepair<br>BEN -<br>BEN - Door 11 had a missing window and the leveler was broken; Door 8 was missing dock leveler brushes; Door 7 leveler brushes deteriorated; Door 10 was left open 2 inches; Door 6 & others nearby - water ingress when raining; Evidence of air gaps observed in some cases when trailers are backed to the door | Major | BAR Dock doors 23 (repeat), 28, 51 (repeat)<br>None of these doors were being used at the time, therefore estimating risk/impact; Two of the three at BAR are repeat findings from last year<br>Many doors were in use and did not allocate resource to evaluate each door at the time of the audit, and as such, there may be additional doors needing attention - suggest comprehensive assessment be performed<br><br>BRU Warehouse overall looked great and showed nice improvement from last year. Nice work Scott and team!<br><br>New or updated procedures, training, auditing, and trending required with appropriate management commitment required to address these findings successfully<br><br>When implement updates | 27 | Monthly audits and proposed action with timeline will be reviewed and approved through senior leadership. | Warehouse management | 15-Oct-22 | | | |
| GMP Inspection | BEN - Warehouse | BEN - poor housekeeping especially around dock doors, inside and out, inclusive of excess wood splinters, trash on ground, and items stored in inappropriate locations | Minor | | 28 | Housekeeping schedules will need to be reviewed to ensure areas are free of trash, debris, and wood splinters. | Tony Grandinetti | 1-Jan-22 | | | |

| SECTION | REQUIREMENT | AUDITOR FINDINGS | RATING | AUDITOR NOTES | CAR # | CORRECTIVE ACTIONS | PERSON RESPONSIBLE | ESTIMATED DATE *(See Comment)* | STATUS | CONFIRMED BY WHO, WHAT | 2022-09-30 NOTES |
|---|---|---|---|---|---|---|---|---|---|---|---|
| GMP Inspection | BEN - Maintenance Shop | REPEAT FINDING (from sister site): FOB risks are not adequately managed / mitigated in BEN Maintenance shop and tracked to entrance of shop Examples:<br>Metal shavings, bolts, nuts, etc found in multiple areas of the floor and cleaning broom FILLED with shavings; No vacuum near appropriate points of use; | Major | BAR Maintenance shop showed significant improvement, had vacuum near the source of contamination, floor was overall clean, chemicals locked, etc. Luis joined us for the tour (2nd shift) and was very engaged and appreciative of any feedback provided. Good work.<br><br>BRU Maintenance shop processes still considered Best Practice (Nice work Dave and team); Two associates joined us and clearly articulated their procedures to clean immediately after their work and before going out on the floor, inclusive of their uniforms | 29 | Ben Maintenance will develop an action plan to ensure FOB are not able to leave the maintenance area. Weekly audit of the area to ensure action plan is working. | Jose Lopez | 1-Oct-22 | | | |
| GMP Inspection | BEN | On Ln250, scale door seals cracked and not appropriately attached to the door, creating potential FOB and micro risks | Major | | 30 | Maintenance manager will review LN250 and submit his recommendation for needed repairs. | Jose Lopez | 15-Sep-22 | | | new parts purchased; should be in next week; look into why like that and not addressed during sanitationand pre-op |
| GMP Inspection | BEN | The method used to cover clean equipment is creating foreign body risks (2 or more pieces of clear plastic torn off of the plastic used to cover equipment after cleaning was found on the scale mezzanine and the steps to the mezzanine. | Major | | 31 | Sanitation will review process for covering and uncovering equipment to determine if a different material or process is needed. | Michael Glowa | 1-Oct-22 | | | |

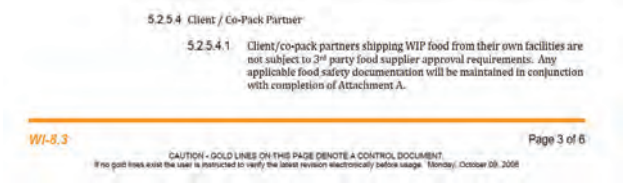
**Exhibit 11**

# RE: Ship # 7001511625 Mondelez (Material # 704620115000)

---

**From:** Erich Zicher
ezicher@cwerksglobal.com
**To:** Mary Madison
mmadison@cwerksglobal.com
**Sent:** Monday, October 24, 2:57 PM

With this coming from Mondelez, we would not necessarily have the GFSI, procedures, questionnaires, etc. See below.

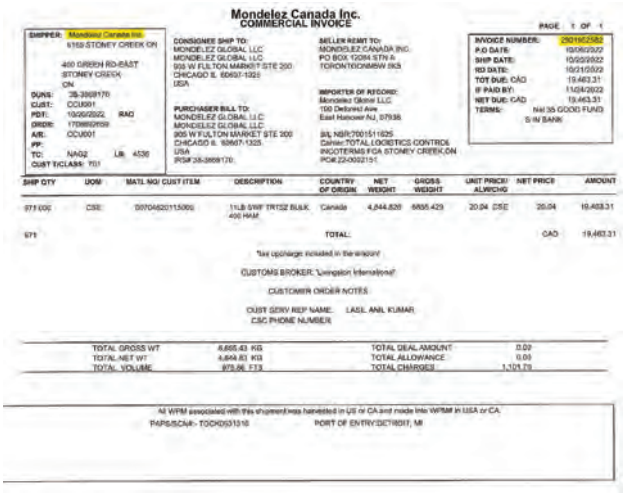


5.2.5.4 Client / Co-Pack Partner

5.2.5.4.1 Client/co-pack partners shipping WIP food from their own facilities are not subject to 3rd party food supplier approval requirements. Any applicable food safety documentation will be maintained in conjunction with completion of Attachment A.

WI-8.3 Page 3 of 6

CAUTION - GOLD LINES ON THIS PAGE DENOTE A CONTROL DOCUMENT.
If no gold lines exist the user is instructed to verify the latest revision electronically before usage. Monday, October 09, 2006



Mondelez Canada Inc.
COMMERCIAL INVOICE

PAGE 1 OF 1

SHIPPER: Mondelez Canada Inc. 9150 STONEY CREEK ON
400 GREEN RD-EAST
STONEY CREEK
ON

DUNS: 25-3808170
CUST: CCU001
PDT: 10/20/2022 RAC
ORDR: 1709892959
A/E: CCU001
FP:
TC: NA02 LB 4536
CUST TCLASS: 701

CONSIGNEE SHIP TO:
MONDELEZ GLOBAL LLC
MONDELEZ GLOBAL LLC
900 W FULTON MARKET STE 200
CHICAGO IL 60607-1325
USA

PURCHASER BILL TO:
MONDELEZ GLOBAL LLC
MONDELEZ GLOBAL LLC
900 W FULTON MARKET STE 200
CHICAGO IL 60607-1325
USA
PO# 25-3808170

SELLER REMIT TO:
MONDELEZ CANADA INC.
PO BOX 12084 STN A
TORONTO ONM5W 0K5

IMPORTER OF RECORD:
Mondelez Global LLC
100 Deforest Ave
East Hanover NJ, 07936

BIL NBR:7001511625
Carrier:TOTAL LOGISTICS CONTROL
INCOTERMS:FCA STONEY CREEK,ON
PO#:2240302151

INVOICE NUMBER: 2901952582
P.O DATE: 10/06/2022
SHIP DATE: 10/20/2022
RD DATE: 10/21/2022
TOT DUE: CAD 19,463.31
IF PAID BY: 11/24/2022
NET DUE: CAD 19,463.31
TERMS: Net 35 GOOD FUND
S-W BANK

| SHIP QTY | UOM | MATL NO/ CUST ITEM | DESCRIPTION | COUNTRY OF ORIGIN | NET WEIGHT | GROSS WEIGHT | UNIT PRICE/ ALW/CHG | NET PRICE | AMOUNT |
|---|---|---|---|---|---|---|---|---|---|
| 973.000 | CSE | 000704620115000 | 11LB SWF TRTS2 BULK 400 HAM | Canada | 4,644.826 | 6665.429 | 20.04 DSE | 20.04 | 19,463.31 |
| 971 | | | TOTAL: | | | | | CAD | 19,463.31 |

Tax upcharge included in the amount

CUSTOMS BROKER: "Livingston International"

CUSTOMER ORDER NOTES

CUST SERV REP NAME: LASE, ANIL KUMAR
CSC PHONE NUMBER

| | | | |
|---|---|---|---|
| TOTAL GROSS WT | 6,665.43 KG | TOTAL DEAL AMOUNT | 0.00 |
| TOTAL NET WT | 4,644.83 KG | TOTAL ALLOWANCE | 0.00 |
| TOTAL VOLUME | 973.06 FT3 | TOTAL CHARGES | 1,101.79 |

All WPM associated with this shipment was harvested in US or CA and made into WPM in USA or CA.
PAPS/SCM#- TOCK053110 PORT OF ENTRY:DETROIT, MI

With this load originating out of Canada, I was more concerned with the Customs approval. I looked this up at https://track.livingstonintl.com/

I attached the Customs tracking information for PO 2901952582 to this email. Let me know if there are any questions

Best,

**Erich Zicher**
Director of Food Safety

1470 Brummel Ave,
Elk Grove Village, IL 60007

Elk Grove Village, IL 60007
+1-630-509-3087 *(office)*
+1-847-826-9424 *(mobile)*
creative-werks.com

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**From:** Mary Madison <mmadison@cwerksglobal.com>
**Sent:** Monday, October 24, 2022 2:40 PM
**To:** Erich Zicher <ezicher@cwerksglobal.com>
**Subject:** FW: Ship # 7001511625 Mondelez (Material # 704620115000)

Hello Erich,

Here is the associated paper work that you asked for regarding the hold that needs to be released.

Warm regards

**Mary Madison**
Quality Regulatory Manager

1470 Brummel Ave,,
Elk Grove Village, IL 60007
773-297-9569 *(mobile)*
creative-werks.com

Complex packaging solutions with speed and peace of mind

---

**From:** Mary Madison
**Sent:** Monday, October 24, 2022 8:12 AM
**To:** usimports@livingstonintl.com
**Cc:** Erich Zicher <ezicher@cwerksglobal.com>
**Subject:** Ship # 7001511625 Mondelez (Material # 704620115000)

Good day,

I hope this email finds you well thus far!

My name is Mary Madison and I am contacting you in regards to the above mentioned product received from you via Total Logistics Control.

Our records do not reflect the address referenced on the paperwork. I have taken the liberty of attaching that paperwork for review. In an effort to keep our records up to date and keep a handle on our food safety/defense, we need to have the addresses vetted in order to release the material for use. As a result, I am asking you to please fill out the attached questionnaire and return it along with the appropriate GFSI certifications that correspond to each address. Also, please identify what type of facility it is. i.e. Distribution Center, Manufacturing, etc.

Additionally, if there are other sites that you ship from that is outside of this site, please follow the same protocol that we can update our records to expedite the release of product received. Further, if it is possible, can you notify us and provide the requested documentation when there is a ship from address that is outside of the current matrix.

If you should have any questions, please feel free to contact me.

I appreciate your time and assistance.

Warm regards,

**Exhibit 12**

## RE: Vendor and items Quality Approval Process

---

**From:** Mary Madison
mmadison@cwerksglobal.com
**To:** Kinda Abu Hawash
khawash@cwerksglobal.com
**Sent:** Tuesday, October 25, 9:25 AM

Good day Kinda,

Hope this finds you well!

It was definitely my pleasure to meet you last week as well.

Thank you for the email and the question.

Currently, what is required, to the best of my knowledge, is filling out our vendor questionnaire and providing a GFSI certification. See attached questionnaire.

Some issues that I have noted are multiple entries on a vendor with differing variances of their names. In addition, there are numerous addresses associated with the vendor entries. This causes a bottleneck and a constraint in releasing material.

I emailed out a vendor consolidation problem statement and recommendations yesterday. I have attached it for your review. Due to these and other factors I believe that we will have to analyze and revamp.

After you review these items, I invite any feedback or dialogue that you may have to share.

Again, I appreciate you reaching out to me. I also appreciate your time, efforts and assistance in this project.

Warmest wishes,

[[#]]
Name: Mary Madison
Phone: 773.297.9569
[[#]]

---

**From:** Kinda Abu Hawash <khawash@cwerksglobal.com>
**Sent:** Monday, October 24, 2022 3:31 PM
**To:** Mary Madison <mmadison@cwerksglobal.com>
**Subject:** Vendor and items Quality Approval Process

Hi Mary,

It was a please meeting you last week. To follow up on our discussion, can you please provide me with the criteria that quality department requires / looks at when approving a new vendor? Also, is there information to provide vendors on the quality approval process that their products go through when delivered at our facilities (soft hold check list maybe)?

Thank you!

creative werks

**Kinda Abu Hawash**
Procurement Specialist

1470 Brummel Ave,
Elk Grove Village, IL 60007
creative-werks.com

Complex packaging solutions with speed and peace of mind

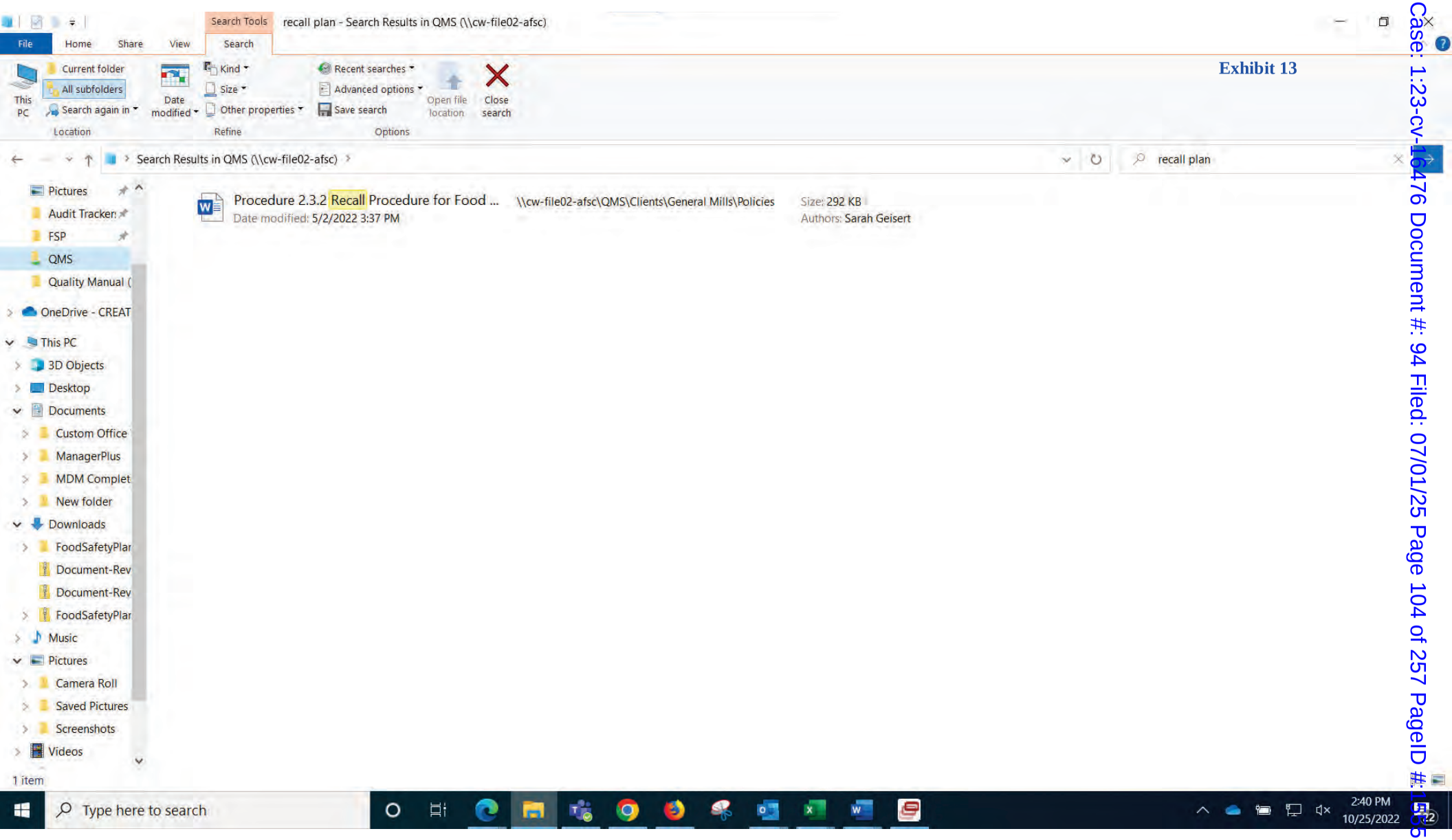
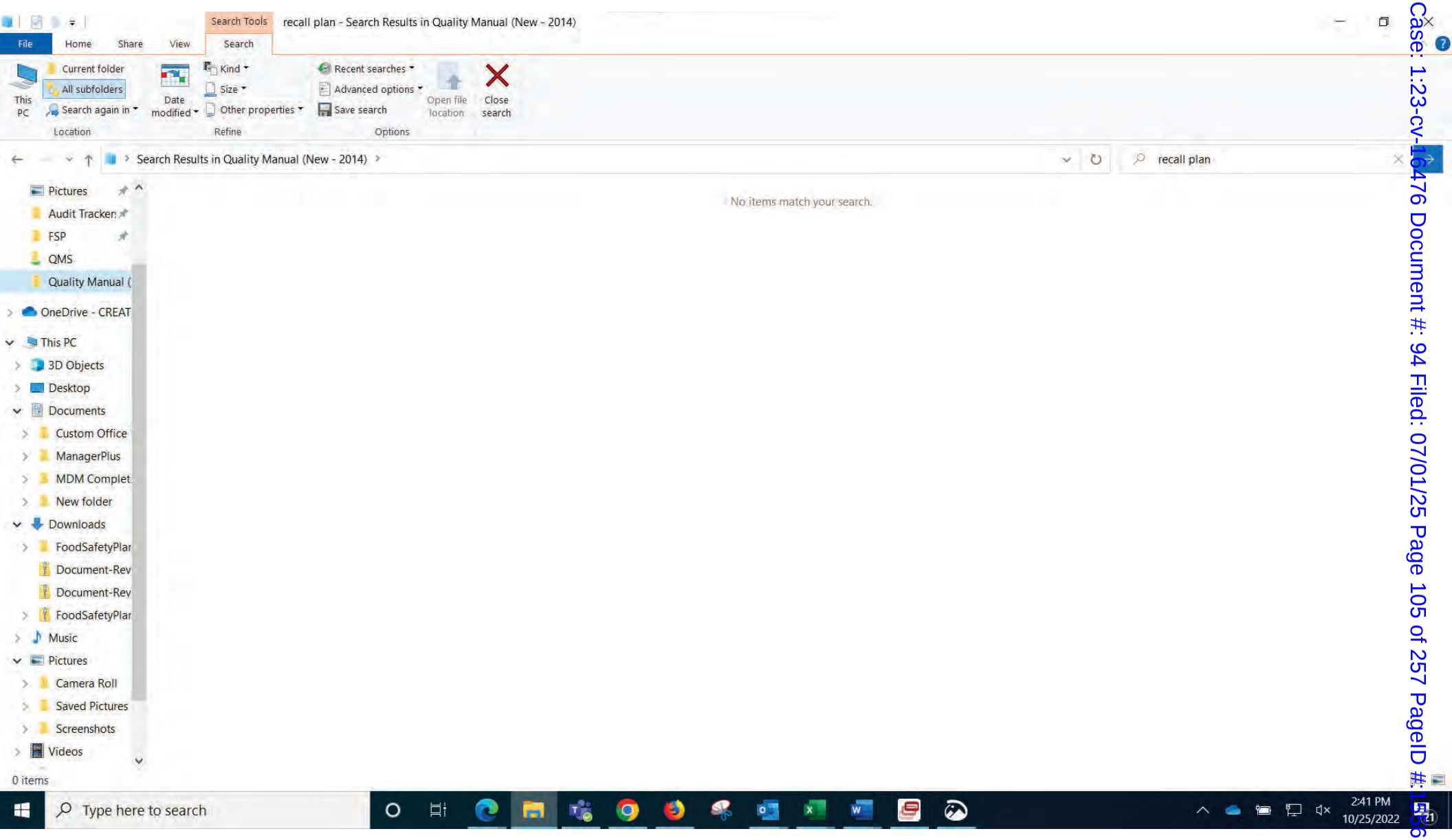



Exhibit 13



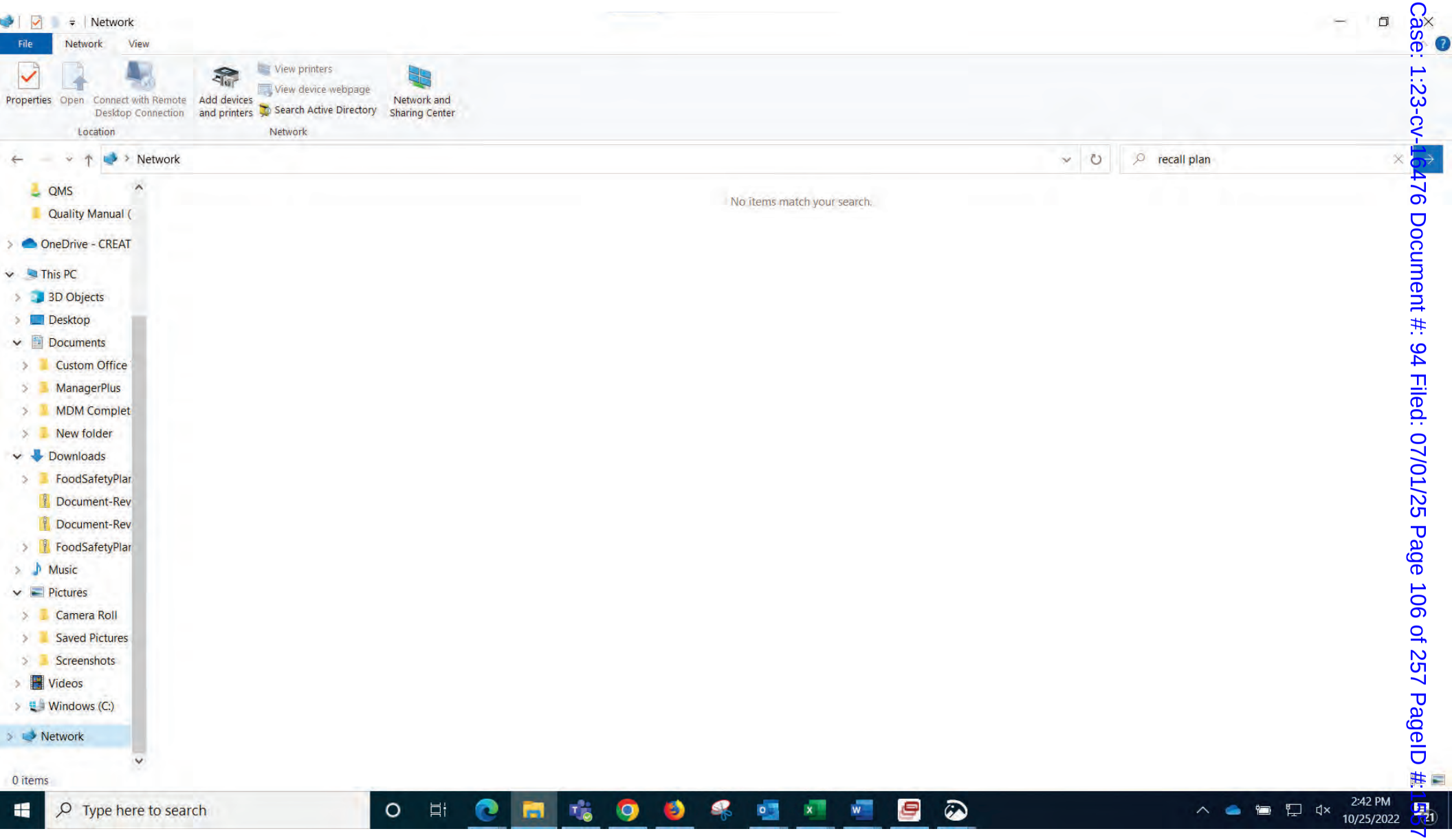


**Exhibit 14**

## RE: TraceGains Doucment Reqest

---

**From:** Erich Zicher
ezicher@cwerksglobal.com
**To:** Mary Madison
mmadison@cwerksglobal.com
**Sent:** Wednesday, October 26, 12:13 PM

Hi Mary,

Thank you for looping me into this issue. Can you please provide me the TraceGains username and password. I would like to go in and see what else we have missing (being 31% and 13% complete would imply a significant number of documents). As for the request on the recall plan, this would be covered in the attached WI. Once I am able to assess what is missing/out of date, I should be able to help you get these files updated more efficiently.

Best,

alt

**Erich Zicher**
Director of Food Safety

1470 Brummel Ave,
Elk Grove Village, IL 60007
+1-630-509-3087 *(office)*
+1-847-826-9424 *(mobile)*
creative-werks.com image image image image

---

**From:** Mary Madison
<mmadison@cwerksglobal.com>
**Sent:** Wednesday, October 26, 2022 7:58 AM
**To:** Erich Zicher <ezicher@cwerksglobal.com>
**Subject:** FW: TraceGains Doucment Reqest

Good day Erich,

Hope this finds you well.

The below mentioned client made a request in December of 2021 for documents and is now

actively seeking documents from us in Tracegains.

I reached out for help a couple of weeks ago to address this issue. In the interim, I have been searching for various documents and have been unsuccessful. For example, the recall plan. From my search, I can find no evidence of such a plan except one specifically for General Mills. See attached

Further, it seems, as I have been looking through the voluminous document requests there are a significant number of documents that I cannot locate that are being requested or that are sorely out of date. I know in our previous conversations, when I raised issue with deficient documentation, you indicated that our clients do not read these documents etc... and it is ok to present them in the current state.

As for me, again, I do not feel comfortable providing them with incorrect or out of date documentation, as these are legal documents that can come back to bite our beloved company in the but with severe consequences, if they are not correct.

Although, this situation did not happen on my watch it is extraordinarily awkward and embarrassing. As you can imagine and understand, this is a process that has many factors, including science, data and our process owners, that contribute to the analysis of the situation. That have to be line balanced to formulate the correct approach and response to the situation.

My initial recommendation to you would be to identify what all of the outstanding documents are in totality to see how to best address all of these outstanding issues. Further, this is not something that can be done without assistance and information. Documents must be customized based upon the client and other weighted factors to ensure that their needs are being met and we

have done our due diligence and it further must be supported by science and properly documented.

Today, due to these circumstances and the clients demand and warranted immediate explanation for the outstanding documents, I am not sure how to approach this situation.

My motto is happy client happy life.

Thank you for your time and assistance in this matter.

Best,

**Mary Madison**
Quality Regulatory Manager

1470 Brummel Ave,,
Elk Grove Village, IL 60007
773-297-9569 *(mobile)*
creative-werks.com

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---

**From:** Khawaja, Awais <Awais.Khawaja@wilton.com>
**Sent:** Tuesday, October 25, 2022 2:27 PM
**To:** Mary Madison <mmadison@cwerksglobal.com>; Jacquelyn LaManna <jlamanna@cwerksglobal.com>; Erich Zicher <ezicher@cwerksglobal.com>
**Cc:** Anita Johnson <aJohnson@cwerksglobal.com>
**Subject:** RE: TraceGains Doucment Reqest



The document percentage didn't move from last two weeks.

Could you please confirm how long does it take to complete the document requirements in

TraceGians?

Thank you,

**Best Regards,**
**Awais Khawaja**
**Quality Specialist**
**Wilton Brands LLC**
**535 East Diehl Road, Naperville, IL 60563**
akhawaja@wilton.com
630-810-2466


---

**From:** Mary Madison <mmadison@cwerksglobal.com>
**Sent:** Tuesday, October 25, 2022 2:14 PM
**To:** Khawaja, Awais <Awais.Khawaja@wilton.com>; Jacquelyn LaManna <jlamanna@cwerksglobal.com>; Erich Zicher <ezicher@cwerksglobal.com>
**Cc:** Anita Johnson <aJohnson@cwerksglobal.com>
**Subject:** RE: TraceGains Doucment Reqest

Hello,

I hope this provides some clarification. I made some inquiries and I am awaiting information to my queries.

Thank you for your time and patience.

Respectfully,

**Mary Madison**
Quality Regulatory Manager

1470 Brummel Ave,,
Elk Grove Village, IL 60007
773-297-9569 *(mobile)*
creative-werks.com




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---

**From:** Khawaja, Awais <Awais.Khawaja@wilton.com>

**Sent:** Tuesday, October 25, 2022 1:35 PM
**To:** Mary Madison <mmadison@cwerksglobal.com>; Jacquelyn LaManna <jlamanna@cwerksglobal.com>; Erich Zicher <ezicher@cwerksglobal.com>
**Cc:** Anita Johnson <aJohnson@cwerksglobal.com>
**Subject:** RE: TraceGains Doucment Reqest



Hello,

Could you please explain a lit bit more?

Thank you,

**Best Regards,**
**Awais Khawaja**
**Quality Specialist**
**Wilton Brands LLC**
**535 East Diehl Road, Naperville, IL 60563**
**akhawaja@wilton.com**
**630-810-2466**


---

**From:** Mary Madison <mmadison@cwerksglobal.com>
**Sent:** Tuesday, October 25, 2022 1:26 PM
**To:** Khawaja, Awais <Awais.Khawaja@wilton.com>; Jacquelyn LaManna <jlamanna@cwerksglobal.com>; Erich Zicher <ezicher@cwerksglobal.com>
**Cc:** Anita Johnson <aJohnson@cwerksglobal.com>
**Subject:** RE: TraceGains Doucment Reqest

Hello

Hope this finds you well.

I am still awaiting a disposition.

Thank you kindly!

Best,

**Mary Madison**
Quality Regulatory Manager

1470 Brummel Ave,,
Elk Grove Village, IL 60007
773-297-9569 *(mobile)*
creative-werks.com

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---

**From:** Khawaja, Awais <Awais.Khawaja@wilton.com>
**Sent:** Tuesday, October 25, 2022 1:22 PM
**To:** Mary Madison <mmadison@cwerksglobal.com>; Jacquelyn LaManna <jlamanna@cwerksglobal.com>; Erich Zicher <ezicher@cwerksglobal.com>
**Cc:** Anita Johnson <aJohnson@cwerksglobal.com>
**Subject:** RE: TraceGains Doucment Reqest

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello,

Just following up!

Any updates?

Thank you,

**Best Regards,**
**Awais Khawaja**
**Quality Specialist**
**Wilton Brands LLC**
**535 East Diehl Road, Naperville, IL 60563**
akhawaja@wilton.com
630-810-2466
image

**From:** Mary Madison <mmadison@cwerksglobal.com>
**Sent:** Friday, October 14, 2022 11:07 AM
**To:** Khawaja, Awais <Awais.Khawaja@wilton.com>; Jacquelyn LaManna <jlamanna@cwerksglobal.com>; Erich Zicher <ezicher@cwerksglobal.com>
**Cc:** Anita Johnson <aJohnson@cwerksglobal.com>
**Subject:** RE: TraceGains Doucment Reqest

Good day,

I am in the process of gathering the necessary information to complete the request. As soon as, I can get it together I will complete the request.

Thank you kindly for your time and patience.

**Mary Madison**
Quality Regulatory Manager

1470 Brummel Ave,,
Elk Grove Village, IL 60007
773-297-9569 *(mobile)*
creative-werks.com

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**From:** Khawaja, Awais <Awais.Khawaja@wilton.com>
**Sent:** Friday, October 14, 2022 10:37 AM
**To:** Mary Madison <mmadison@cwerksglobal.com>; Jacquelyn LaManna <jlamanna@cwerksglobal.com>; Erich Zicher <ezicher@cwerksglobal.com>
**Cc:** Anita Johnson <aJohnson@cwerksglobal.com>
**Subject:** RE: TraceGains Doucment Reqest



Hello,

Any updates on below request?

Thank you,

**Best Regards,**
**Awais Khawaja**
**Quality Specialist**
**Wilton Brands LLC**
**535 East Diehl Road, Naperville, IL 60563**
akhawaja@wilton.com
630-810-2466


---

**From:** Khawaja, Awais
**Sent:** Wednesday, October 12, 2022 8:12 AM
**To:** Mary Madison <mmadison@cwerksglobal.com>; Jacquelyn LaManna <jlamanna@cwerksglobal.com>; Erich Zicher <ezicher@cwerksglobal.com>
**Cc:** Anita Johnson <aJohnson@cwerksglobal.com>
**Subject:** RE: TraceGains Doucment Reqest

Good Morning,

The both locations are still missing quite a bit of documents. The Bensenville is on 31% and Elk Grove is on 13%.

Thank you,

**Best Regards,**
**Awais Khawaja**
**Quality Specialist**
**Wilton Brands LLC**
**535 East Diehl Road, Naperville, IL 60563**
akhawaja@wilton.com
630-810-2466


---

**From:** Mary Madison <mmadison@cwerksglobal.com>
**Sent:** Tuesday, October 11, 2022 10:58 AM
**To:** Jacquelyn LaManna

<jlamanna@cwerksglobal.com>; Erich Zicher
<ezicher@cwerksglobal.com>
**Cc:** Khawaja, Awais
<Awais.Khawaja@wilton.com>; Anita Johnson
<aJohnson@cwerksglobal.com>
**Subject:** RE: TraceGains Doucment Reqest



Good day all,

I have uploaded the most current WI regarding one (1) of the outstanding issues. However, I am unable to access the issue to address it. Can you please assist me in understanding what the issue is that I may resolve it expeditiously.

Kind regards

**Mary Madison**
Quality Regulatory Manager

1470 Brummel Ave,,
Elk Grove Village, IL 60007
773-297-9569 *(mobile)*
creative-werks.com

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---

**From:** Mary Madison
**Sent:** Tuesday, October 11, 2022 10:37 AM
**To:** Jacquelyn LaManna
<jlamanna@cwerksglobal.com>; Erich Zicher
<ezicher@cwerksglobal.com>
**Cc:** Khawaja, Awais
<Awais.Khawaja@wilton.com>; Anita Johnson
<aJohnson@cwerksglobal.com>
**Subject:** RE: TraceGains Doucment Reqest

Good day all,

I will be more than happy to assist.

Let me check it out and get back with a disposition.

Kind regards,

---

**From:** Jacquelyn LaManna <jlamanna@cwerksglobal.com>
**Sent:** Tuesday, October 11, 2022 9:52 AM
**To:** Mary Madison <mmadison@cwerksglobal.com>
**Cc:** Khawaja, Awais <Awais.Khawaja@wilton.com>; Anita Johnson <aJohnson@cwerksglobal.com>
**Subject:** FW: TraceGains Doucment Reqest

Good morning Mary,

Could you help with the below request from Awais. We have a few quality documents that are still needing to be filled out on TraceGains.

Thanks,

**Jacquelyn LaManna**
Project Manager

1470 Brummel Ave,
Elk Grove Village, IL 60007
+1-630-509-3039 *(office)*
creative-werks.com

---

**From:** Khawaja, Awais <Awais.Khawaja@wilton.com>
**Sent:** Friday, September 23, 2022 4:09 PM
**To:** Anita Johnson <aJohnson@cwerksglobal.com>; Jacquelyn LaManna <jlamanna@cwerksglobal.com>
**Subject:** TraceGains Doucment Reqest

Hi Jacquelyn and Anita,

I saw you guys started the document upload process in TraceGains but its sitting on 18% and 4%. Could you please start reviewing the document requirements in TraceGains and complete the list.

Please let me know if you have any question.

Thank you,

**Best Regards,**
**Awais Khawaja**
**Quality Specialist**
**Wilton Brands LLC**
**535 East Diehl Road, Naperville, IL 60563**
akhawaja@wilton.com
630-810-2466

**Exhibit 15**

## RE: Food Safety Plans

---

**From:** Mary Madison
mmadison@cwerksglobal.com
**To:** Erich Zicher ezicher@cwerksglobal.com
**Sent:** Thursday, October 20, 1:54 PM

Good day Erich,

I still have some questions about the FSCPA training material you provided to me yesterday as your template for the FSP.

When I read through the material and looked at the Dunkaroos' FSP I am unable to see any reference(s) to where you obtained the information cited in the FSP. I cannot make that direct correlation. I am sure that I am overlooking your reference points.

Also, the FDA reference material you referred to that I had cited in my writing sampling does not support the findings either.

I have been trying to find the correlation.

Also, I am trying to understand what is the basis for your findings in the analysis. Also, how did you construct the analysis/evaluation for the hazards?

Thank you again for your time and assistance.
Best,
[[#]]
Name: Mary Madison
Phone: 773.297.9569
[[#]]

---

**From:** Erich Zicher <ezicher@cwerksglobal.com>
**Sent:** Wednesday, October 19, 2022 1:24 PM
**To:** Mary Madison
<mmadison@cwerksglobal.com>
**Subject:** RE: Food Safety Plans

FYI

**Erich Zicher**
Director of Food Safety

1470 Brummel Ave,
Elk Grove Village, IL 60007
+1-630-509-3087 *(office)*
+1-847-826-9424 *(mobile)*
creative-werks.com

---

**From:** Mary Madison <mmadison@cwerksglobal.com>
**Sent:** Monday, October 17, 2022 8:26 AM
**To:** Erich Zicher <ezicher@cwerksglobal.com>
**Subject:** RE: Food Safety Plans

Good day Erich,

Hope this finds you well and your days is off to a fantastic start!

I have a few more questions about the plan.

You mentioned to me that you extracted some of the FDA plan to construct the Dunakaroo's FSP, can you tell me framework used to choose those specific line items from the FDA plan to construct the Dunkaroo plan.

I appreciate your time.

Warm regards,

**Mary Madison**
Quality Regulatory Manager

1470 Brummel Ave,,
Elk Grove Village, IL 60007
773-297-9569 *(mobile)*
creative-werks.com



---

**From:** Erich Zicher <ezicher@cwerksglobal.com>
**Sent:** Thursday, October 13, 2022 9:00 AM
**To:** Mary Madison

<mmadison@cwerksglobal.com>
**Subject:** RE: Food Safety Plans

Angie never added dates to the cover page, but it is a live document.

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**Erich Zicher**
Director of Food Safety

1470 Brummel Ave,
Elk Grove Village, IL 60007
+1-630-509-3087 *(office)*
+1-847-826-9424 *(mobile)*
creative-werks.com

---

**From:** Mary Madison <mmadison@cwerksglobal.com>
**Sent:** Thursday, October 13, 2022 8:48 AM
**To:** Erich Zicher <ezicher@cwerksglobal.com>
**Subject:** RE: Food Safety Plans

Hi Erich,

One (1) more question please, is this a WIP or completed doc.

Thanks

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**Mary Madison**
Quality Regulatory Manager

1470 Brummel Ave,,
Elk Grove Village, IL 60007
773-297-9569 *(mobile)*
creative-werks.com



---

**From:** Erich Zicher <ezicher@cwerksglobal.com>
**Sent:** Thursday, October 13, 2022 8:31 AM
**To:** Mary Madison <mmadison@cwerksglobal.com>
**Subject:** RE: Food Safety Plans

Confirmed.

**Erich Zicher**
Director of Food Safety

1470 Brummel Ave,
Elk Grove Village, IL 60007
+1-630-509-3087 *(office)*
+1-847-826-9424 *(mobile)*
creative-werks.com

---

**From:** Mary Madison <mmadison@cwerksglobal.com>
**Sent:** Thursday, October 13, 2022 8:01 AM
**To:** Erich Zicher <ezicher@cwerksglobal.com>
**Subject:** Food Safety Plans

Good day Erich,

Hope all is well!

I would like to confirm that the model to be used for the Food Safety Plan is the one for Dunkaroos.

Thank you for your time.

**Mary Madison**
Quality Regulatory Manager

1470 Brummel Ave,,
Elk Grove Village, IL 60007
773-297-9569 *(mobile)*
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**United States Food and Drug Administration**

**Consumer Complaint / Injury Report**

**Exhibit 16**

This is an accurate reproduction of the original electronic record as of 03/01/2023

**COMPLAINT # 177322**

| Complaint Date | Receiving Organization | Accomplishing District | How Received | Complaint Source | Complaint Received By | Complaint Status |
|---|---|---|---|---|---|---|
| 10/20/2022 | BLT-DO | CHI-DO | Telephone | Consumer | Johnson,Jacqueline | In Progress - Pending Evaluation |

**Complainant Identification**

| Name | Address |
|---|---|
| (b) (6) | |

| Phone (W) | Phone (H) | Source POC Name | Source Phone |
|---|---|---|---|
| | (b) (6) | | |

**Complaint/Injury**

| Complaint Description | Adverse Event Result | Adverse Event Date | Injury / Illness |
|---|---|---|---|
| The complainanted reported on October 18, 2022 she purchased one box of (b) (4) from (b) (4) SuperMarket. Upon arrival to her home she placed the unopened box of cereal on the top of her refrigerator. On October 19th the complainant, her (b) (6) daughter and her (b) (6) consumed the (b) (4) cereal. The complainant stated that she consumerd on bowl with milk, and then later dry cereal placed inside a ziploc bag. The complainants daughter consumed on bowl of the cereal with (b) (4) Milk and her son consumed two large bowls with 2% Milk. The complainant stated that within 1/2 hours she began to experience abdominal pains and gas; and within one hours she developed nausea, vomitting and diarrhea which last for 24 hours. She reported that her son and daughter both became ill with diarrhea as well. The complainant reported that no one in the family suffers with allergies. They did not seek medical attention. A 72 hour food history was requested from the family members who consumed the product. | Non-Life Threatening Injury/Illness - No Adverse Event Reporting | 0ctober 19, 2022 | Gastrointestinal distress |

| Notify OEO? | Notification Date | Attended Health Professional? | Required Hospitalization? | Emergency Room / Outpatient Visit? | Reported Complaint To? | Need addnl. FDA Contact? |
|---|---|---|---|---|---|---|
| Yes | 10/21/2022 | No | No | No | Not Reported to Manufacturer | Unknown |

**Remarks**

10/21/2022 additional information requested. CC form and 72 hour food history was requested from all members of the familly who consumed the product.
Milk:
(b) (4) 2% purchased on October 8, 2022 via Amazon Fresh Net Wt. 1 Gallon Lot# (b) (4) Expiration Oct 25, 2022 Bar Code: (b) (4) Distributed by: Amazon.com LLC (b) (4) Lactate 2% Reduced Fat Milk purchased on Octobewr 18, 2022 (b) (4) SuperMarket 1/2 Gallon Lot# (b) (4) Expiration Date Dec 2, 2022 Barcode (b) (4) Distribute by: (b) (4)
10/27/2022 spoke with general mills representative who will call back/or email with mfg plant information and case #.
11/2/2022 received email from (b) (6), Information Specialist, (b) (4)

(b) (4); she provided the manufacturer information

**Complaint Symptoms**

| Sympton | System Affected | Onset Time | Duration | Remarks |
|---|---|---|---|---|
| Vomiting | GASTROINTESTINAL | 1 Hours | 24 Hours | developed nausea and vomitting within one hour and lasting approximately 24 hours |
| Diarrhea | GASTROINTESTINAL | 1 Hours | 24 Hours | developed diarrhea one hour lasting 24 hours |
| Abdominal cramps | GASTROINTESTINAL | Immediate | 24 Hours | Gas and stomach pain thirty minutes after consuming milk and cereal |

**Health Care Professional**

| Provider Name | Address | Phone | Occupation |
|---|---|---|---|

**Hospital Information**

| Hospital Name | Address | Phone | Dates of Stay |
|---|---|---|---|

**Emergency Room/Outpatient Visit**

| Hospital Name | Address | Phone | ER Date |
|---|---|---|---|

**Product and Labeling**

| Brand Name | Product Name | Product Code | Product Description | PAC | UPC Code |
|---|---|---|---|---|---|
| (b) (4) | (b) (4) | 05YFE99 | Cereal Preparations Not Elsewhere Mentioned, N.E.C.;Paper;Commercially Sterile | 03R801 | 016000156432 |

| Qty / Unit / Package | Lot/ Serial # | Exp/Use by Date | Purchase Date | Product Used | Amount Consumed/Used |
|---|---|---|---|---|---|
| 32 Ounces Box | (b) (4) | 09/02/2023 | October18, 2022 | Yes | |

| Date Used | Date Discontinued | Amount Remained | Imported Product? | Country of Origin | Label Remarks |
|---|---|---|---|---|---|
| | | | No | United States | |

**Retail**

| Name | Address |
|---|---|
| (b) (4) SuperMarket | (b) (4) |

**Problem Ingredient Group**

**Complaint # 177322**

**Manufacturer/Distributor**

| FEI | Name & Address | Home District | Firm Type |
|---|---|---|---|
| 3011417063 | Creative Werks 1350 Munger Rd Bartlett Illinois United States 60103-1698 | CHI-DO | Manufacturer |

**Initial Evaluation/Initial Disposition**

| Problem Keyword | Problem Keyword Details |
|---|---|
| Allergic Reaction | Vomitting, Diarhea, Headache Abdominal pain |

| Initial Evaluation | Initial Disposition | Disposition Made By | Disposition Date |
|---|---|---|---|

**Initial Disposition Remarks**

11/2/2022 received manufacturer information from (b) (6), Information Specialist, (b) (4) (b) (4)

**Referrals**

| Org Name | HHS Mail Code |
|---|---|

**There are no Cosmetics details for this Complaint.**
**There are no Adverse Event details for this Complaint.**

**Related Complaints**

**Complaint #177322**

## COMPLAINTS FOLLOW - UP

### Grouped Follow - Up Operations

| Operation Id | Operation Code | Assignment Number | Accomplishing Organization | Performing Organization | Sample Number | PAF | Status | Status Date |
|---|---|---|---|---|---|---|---|---|

**There are no Follow Up Operations related to this complaint.**

### Disposition Summary

| Is Consumer Responsible? | Responsible FEI | Address | Name | Firm Type |
|---|---|---|---|---|

**Follow-Up Disposition** **Disposition Made By** **Disposition Date**

**Disposition Remarks**

### Follow-Up Sent To

| Organization Name | HHS Mail Code |
|---|---|

**Exhibit 17**

## RE: Informational Meeting

---

**From:** Mary Madison
mmadison@cwerksglobal.com
**To:** Gretchen LeMay
glemay@cwerksglobal.com
**Sent:** Friday, October 21, 8:25 AM

Hi Ms. Lemay,

Thank you for your response!

Monday is sufficient.

Thank you kindly!

Have an awesome weeked.

Warm regards,
[[#]]
Name: Mary Madison
Phone: 773.297.9569
[[#]]

---

**From:** Gretchen LeMay
<glemay@cwerksglobal.com>
**Sent:** Thursday, October 20, 2022 1:55 PM
**To:** Mary Madison
<mmadison@cwerksglobal.com>
**Subject:** RE: Informational Meeting

Hi Mary

Apologies for the late response. I am unfortunately in meetings the rest of the day and a good chunk of tomorrow so maybe Monday? If there is something specific you need info on (payroll, benefits etc) please let me know and I can have somebody from the team reach out.

Thanks
Gretchen

**Gretchen LeMay**
Head of People / Corporate Vice President

creative werks

1470 Brummel Ave,
Elk Grove Village, IL 60007
630-422-3587 *(office)*
creative-werks.com

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---

**From:** Mary Madison <mmadison@cwerksglobal.com>
**Sent:** Thursday, October 20, 2022 8:27 AM
**To:** Gretchen LeMay <glemay@cwerksglobal.com>
**Subject:** Informational Meeting

Good day Ms. LeMay,

I hope this email finds you well!

I am Mary Madison and I do not believe we have met as of yet.

I would like a few moments of your time to speak with you sometime today or tomorrow.

Please advise.

Thanking you in advance for your time and consideration!

Warm regards,

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**Mary Madison**
Quality Regulatory Manager

1470 Brummel Ave,,
Elk Grove Village, IL 60007
773-297-9569 *(mobile)*
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**Exhibit 18**

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# REGULATORY BUSINESS PROBLEM

October 20, 2022

ABSTRACT

Creative Werks LLC's non-compliance to the relevant statutes, standards and regulations under FSMA is an inherent systematic and systemic issue throughout the organization that creates irreparable harms for all stakeholders.

Mary Madison
Quality Regulatory Manager

## Summary of Problem Statement

Creative Werks LLC's non-compliance with the relevant statutes, standards and regulations under FSMA is an inherent systematic and systemic issue throughout the organization that creates irreparable harms for all stakeholders. More specifically for Creative Werks LLC, this non-compliance creates legal liability and culpability due to our breach of contract, breach of fiduciary duty and falsifying documents, among other things, to our clients, the managing members of Creative Werks LLC, governmental regulatory agencies, the end users and society at large. Civil and criminal remedies are results of such liability and can be comprised of monetary judgements, fines, penalties, sanctions, suspension of operations and incarceration or a combination thereof. Other stakeholders could suffer injury, illness or death; in addition, others can suffer loss of employment and economic instability.

## Problem Statement

Analysis of the current Food Safety Plans at Creative Werks LLC., evidences that Creative Werks LLC., has year over year, consistently been out of regulatory compliance with the Federal Food, Drug, and Cosmetic Act "hereinafter" (FD&C Act), as amended by the Food Safety Modernization Act "hereinafter" FSMA and its relevant subparts.

Further analysis suggests that there is no cognitive recognition that the Food Safety Plans are out of legal compliance with FSMA. *(See Exhibit A)* Nor is it readily apparent that the lack of compliance is a causal connection to outstanding audit/compliance issues with current customers. *(See Exhibit B*) Also, it can be reasonably inferred that there is a high probability factor that our non-compliance is a root cause in lost business opportunities, such as Pepsi. Further, there is no evidence that a formidable plan of action is in place or being developed to remediate the noncompliance and outstanding compliance issues. *(Exhibit C)*

Moreover, analysis suggests that there has been a failure to apply the relevant statutes, standards and regulations. Additionally, there has been an improper interpretation, analysis and application of the relevant statutes, standards and regulations relative to the business unit's objectives of manufacturing, co-packing and compliance.

## Stakeholders

One hundred percent (100%) of our client, customer and vendor base is subject to the regulatory framework and guidance of the FD&C Act, as amended by FSMA.

One hundred percent (100%) of the end users are protected by the regulatory framework and guidance of the FD&C Act, as amended by FSMA.

One hundred percent (100%) of our organization is governed by the regulatory framework and guidance of the FD&C Act, as amended by FSMA.

## Compliance

Compliance is achieved by adherence to the relevant statutes, standards and regulations under FSMA and other regulatory schemes. Further, compliance is underscored by overlap and continuity of customer requirements and Creative Werks LLC's protocol's, procedures and policies; coupled, with robust communication and risk management plans skewed to the relevant statutes, standards and regulations under FSMA and other regulatory schemes.

Compliance is not achieved through buzzwords or the sole expressed use of Continuous Improvement methodologies and tools. Additionally, quality and compliance are often treated and used interchangeably; however, there is a vital difference between these two terms. Specifically, regulatory compliance is compulsory and must be followed by any business wishing to engage in the stream of commerce.

Non-compliance negatively affects our sustainability, goodwill, and profitability here at Creative Werks LLC. In addition, it creates a public health threat and potential public health crisis.

## Risks

A vast range of inherent risks exist that impacts our organization; such as, customer supplied/source suppliers to supplier/vendor performance matrices to allergen control among other risk factors. Risks can either be business or regulatory risks or a combination of both risks thereof. Each risk is to be evaluated cumulatively for maximum optimization, including internal risks. Further, there are risks associated with training, scientific validation and verification, monitoring, documentation, and recordkeeping that must be line balanced for verification of implementation and effectiveness, as required by law.

Ongoing risk management is essential in this ever-changing environment. This proactive stance helps protect our brand reputation and business while creating operational efficiencies. Failure to build mitigation strategies around business and compliance risks identified, forecloses opportunities to improve, avoid complacency and litigation.

## Cost of Doing Nothing

Since the inception of the Preventive Controls regulations, Creative Werks LLC has never been compliant and has had repeated violations from numerous customer audits. We also have approximately 139 open document requests from various customers that have been outstanding since 2021 that are inextricably linked to our non-compliance. *(See Exhibit D)* We also have lost business opportunities that translate into the loss of dollars, profitability and goodwill; translating into market share loss. Further, we have noted infractions and/or violations from the FDA for non-compliance that are available for public inspection and review.

Also, a culture that is diametrically opposed to the transparency mantra of Creative Werks LLC has evolved. Further, this culture exhibits and encourages a blatant disregard for the law. Additionally, this

conduct is in direct contravention to domestic and international regulatory framework used for transparency to promote and underscore food protection initiatives.

If we do nothing, we can expect more of these and other scenarios; along with an increase in lost revenue, increased legal exposure and lawsuits among other things.

Further if we do nothing, we will also be in violation of other subparts of FSMA that require us to act swiftly in implementing an immediate course correction among other things. Failure to act swiftly within the prescribed time frame will also subject us to additional civil and criminal liabilities for once again failing to comply with the standards.

## Legal Exposure

Legal liability is triggered each and every day that compliance is not achieved. It also occurs on a transactional level on multiple fronts for all stakeholders.

Legal liability is governed by statutes of limitations relative to the claims asserted that are tied to either state or federal laws.

For example, product liability has a two (2) year statute of limitation. The statute of limitation is triggered when the person becomes aware that they have been harmed.

E.g. the incident raised, by the FDA in its September 2022 inspection, relative to product failure in conjunction with Pepsi that was reported in October of 2021. This incident has an expiry date for civil liability of October 2023. Criminal liability has no statute of limitation.

Another example is our current production of Valentine and Easter products the legal exposure is two (2) years beyond an adverse event. i.e. after product distribution and consumption by the end user. This pushes this liability exposure out past Valentine and Easter of 2025.

Further, most recently legal precedent supports that insurance companies reject indemnifying insureds for breach of any fiduciary duty; including non-compliance; thus, leaving us to settle any outstanding judgments at law or debts with company assets.

## Recommendations:

Implement an immediate course correction.

Refrain from hiring any persons or purchasing any compliance aids until a needs assessment is conducted and analyzed that supports a formidable plan of action accompanied by a supporting business case.

Implement proper oversight.

Identify, interpret and apply the proper relevant statutes, standards and regulations necessary to achieve compliance.

Line balance the appropriate standards against customer requirements.

Develop, implement and sustain communication plans.

Implement a Risk Management program.

Contract Management

Choose a certification that synergizes all the necessary elements for compliance and success.

Answer questions as asked; speak only to issues at hand.

Refrain from comingling facts from various situations or instances.

Refrain from comingling relevant statutes, standards and regulations during audit and inspection proceedings.

### Other Recommendations:

Restructure Creative Werks LLC to a series LLC to reduce liability and exposure. i.e. Have a series LLC for each client or venture.  E.g. Creative Werks-PepsiCo LLC

**Exhibit 19**

creative werks
1470 Brummel Ave
Elk Grove Village, IL 60007
www.creative-werks.com
630.860.2222

## Notice of Suspension

October 26, 2022

Mary Madison
Quality Regulatory Manager
Via Hand Delivery

Dear Mary,

This letter is to inform you that you are being placed on a paid suspension effective immediately. This suspension will last until a full investigation into the statements made in your report and during your conversation with Steve Schroeder on Friday, October 21, 2022 can be fully completed. This review will be conducted by an outside attorney and Human Resources will make the introduction when the time comes.

During your suspension you will be paid at your regular rate of pay and have access to benefits. You will not have access to any IT systems or the building until the investigation is complete.

If you have further questions, please reach out the HR team as needed.

Thank you,

Gretchen LeMay
Head of People

**Exhibit 20**

Gmail **Mary Madison <assist2law@gmail.com>**

# Attorney Interview- Tomorrow

**Gretchen LeMay** <glemay@cwerksglobal.com> Tue, Nov 8, 2022 at 1:21 PM
To: Mary Madison <assist2law@gmail.com>

Mary

Per your request, attached please find a zip file that contains your onboarding documents that you completed prior to your employment along with your suspension letter.

Thank you for providing your counsel's availability. Unfortunately, that will not be a long enough window of time to conduct the investigation as our outside counsel estimates needing 3-4 hours to speak with you.

We have been trying to have this meeting for over a week while you have been on paid suspension. Our counsel was prepared to meet with you promptly last week, but you did not show up for the meeting. Please speak with your counsel and provide availability for 3-4 hours to meet with our investigator. Until that meeting takes place you will be put on unpaid suspension. We will not continue to pay you while delays on your part remain. You will be paid through today and for any time spent meeting with our investigator.

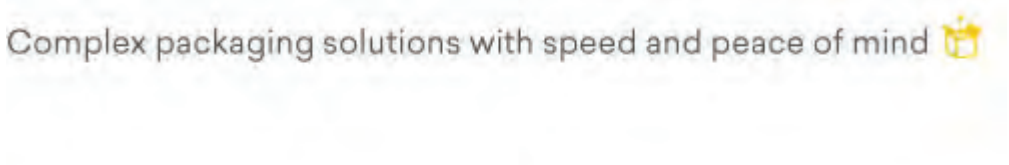
Thank you,

Gretchen

creative werks

Gretchen LeMay
Head of People / Corporate Vice President

1470 Brummel Ave,
Elk Grove Village, IL 60007
630-422-3587 *(office)*
creative-werks.com




**From:** Mary Madison <assist2law@gmail.com>
**Sent:** Monday, November 7, 2022 5:03 PM

**To:** Gretchen LeMay <glemay@cwerksglobal.com>
**Subject:** Re: Attorney Interview- Tomorrow



Good day Ms. LeMay,

As promised here is the counselor's availability.

1:00 pm-2:00 pm on 11.18.2022

2:00 pm-3:00 pm on 11.29.2022

12:00 pm-1:00 pm on 11.30.2022

Further, I am requesting a copy of my entire personnel file under the Illinois personnel Review Act.

Thank you for your time and assistance in these matters.

Best regards,

Mary Madison

On Mon, Nov 7, 2022 at 7:38 AM Mary Madison <assist2law@gmail.com> wrote:

> Good day Ms. LeMay
>
> I will have counselor's availability this afternoon and will provide it at that time.
>
> Best Regards
>
> Mary Madison
>
> On Fri, Nov 4, 2022, 8:21 AM Mary Madison <assist2law@gmail.com> wrote:
>
> > Good day Ms. LeMay,
> >
> > I am awaiting a return call and will forward you that information up receipt.

Thank you for your time and assistance in this matter.

Respectfully

Mary Madison

On Thu, Nov 3, 2022 at 8:36 AM Gretchen LeMay <glemay@cwerksglobal.com> wrote:

> Hi Mary,
>
> I'm not going to debate what your interpretation or understanding is of our prior conversation. The fact is that we have an ongoing investigation, the company has retained an outside investigator, and the investigator would like to meet with you to gather information.
>
> While we don't typically allow an employee to have counsel present during a company investigation, we will make an exception in this situation because we want to make sure you have an opportunity to provide information so that the investigator has that information as part of her findings. Please understand that your counsel will not be allowed to interfere with the interview but may be present if you like.
>
> Since you are still being paid while not working as the investigation proceeds, we would like you to meet with the investigator as soon as possible. Please provide your counsel's availability to me today so that we can arrange for the meeting.
>
> Thank you,
>
> Gretchen

creative werks

**Gretchen LeMay**
Head of People / Corporate Vice President

1470 Brummel Ave,
Elk Grove Village, IL 60007
630-422-3587 *(office)*
creative-werks.com

Complex packaging solutions with speed and peace of mind

---

**From:** Mary Madison <assist2law@gmail.com>
**Sent:** Wednesday, November 2, 2022 11:17 AM
**To:** Gretchen LeMay <glemay@cwerksglobal.com>
**Subject:** Re: Attorney Interview- Tomorrow



Good day Ms. LeMay

I have no problem following up with you or anyone else in regards to the risk assessment prepared and submitted to Mr. Schroeder on October 21, 2022. However, the rub is the circumstances that surround the matter.

Moreover, the email you are referencing, as an incorrect interpretation based upon your interpretation, is my interpretation of what you stated to me during our meeting October 26, 2022. Further, I am certain that it was my understanding that you stated that you had conducted an investigation that conclusively found my risk assessment(s) unfounded prompting my suspension. Based upon those findings you indicated that it warranted a need to get outside counsel involved.

I am alarmingly concerned as you reference this matter as an internal matter that is now using external resources presumably for the protection of the company's interest. Further, it is hard and difficult for me to look at the actions taken against me and the conversations that I have had relative to this matter and not logically deduce that: 1) my risk assessments were not received as correct and that; 2) there was something that was identified by you and others that supported the fact I allegedly committed some type of malfeasance to warrant such a drastic measure of suspension. Further, at no time could you provide me with those relevant details.

Contrarily, if my interpretation is not correct, then am I to understand that there was no investigation that led up to me being suspended?

Again, I have no problem defending the risk identified. However, the conversation that I had with you, the actions taken against me and involvement of outside counsel leads me to believe otherwise. I contend that based upon these circumstances and inconsistencies, I require legal representation, when I speak to the outside counsel, whose recommendations and findings will be used as a determinative factor in this matter.

Thank you for your time and assistance in this matter.

Mary Madison

On Wed, Nov 2, 2022 at 7:14 AM Gretchen LeMay <glemay@cwerksglobal.com> wrote:

> Mary
>
> Your below email does not correctly recap the conversation we had last week. You were suspended pending the results of an investigation that included an interview that needed to happen with you which is scheduled for this morning. For an internal matter employees do not need or require counsel to be present.
>
> Given that you are on a paid suspension there should be no reason that you cannot meet with Kim as scheduled this morning.
>
> Thank you,
>
> creative werks
>
> **Gretchen LeMay**
> Head of People / Corporate Vice President
>
> 1470 Brummel Ave,
> Elk Grove Village, IL 60007
> 630-422-3587 *(office)*
> creative-werks.com
>
> Complex packaging solutions with speed and peace of mind
>
> ---
>
> **From:** Mary Madison <assist2law@gmail.com>
> **Sent:** Wednesday, November 2, 2022 2:13 AM
> **To:** Gretchen LeMay <glemay@cwerksglobal.com>
> **Subject:** Re: Attorney Interview- Tomorrow

Good day Ms. LeMay

I am in receipt of your 4:40 pm email and voice mail, of November 1, 2022, regarding an interview with the company's outside counsel on November 2, 2022. When you, Wendy and I last spoke on Wednesday, October 26, 2022, you indicated that I was being suspended for the conversation that I had with Mr. Schroder on Friday, October 21, 2022.

When I asked why I was being suspended, you indicated that you conducted an investigation that concluded that the issues raised in the risk assessment that I prepared, as the quality regulatory manager, for Mr. Schroder were totally unfounded.

In seeking to better understand the scope of the investigation, I repeatedly asked what the investigation entailed. Each time, you declined to share any information including what those findings were. It was after those requests that you stated that you reviewed my emails and I had also violated a company policy by allegedly sending company property to an outside email address, as a further reason for my suspension. In seeking further clarification, regarding sending company property to an outside email, I asked you a couple of times what was sent? You stated it was something related to the Dunkaroo's account. To which, I categorically deny such an action. You also cited my assertion in the risk assessment that the company had made false statements as the main contributing factor for my suspension.

In support of my contentions, I offered you a report that underscored issues raised in the risk assessment; which, in my opinion, would have brought clarity to the situation. However, you refused to review it and further suggested that I present it to the outside counsel. As such, the adverse employment decision to discipline me with suspension was made without affording me an opportunity to participate in the investigation.

After careful consideration and my inability to reconcile the purpose for speaking with outside legal counsel, I believe that I too need legal counsel when I speak with the company's outside counsel. In light of the circumstances, the discipline against me suggests, I need legal counsel to protect my interest.

Further, being suspended feels more like a punishment for raising issues relative to non-compliance. In my opinion, this goes against the very spirit of the purported open door policy and transparency mantra of "see something say something" that is touted in this organization. I believe this discipline goes against the purpose for which I was hired.

As a direct result of not understanding this process and my desire to protect my interest and rights, I am exercising my right to have legal counsel present during this interview. Further, you stated that you would be in contact with me within a day or so to arrange this meeting. However, almost a week later contact is made for a next day appointment. Due to this short notice, I will need time to arrange for my counsel's availability for any meeting with the company's outside counsel.

Thank you for your time, consideration and assistance in this matter.

Mary Madison

On Tue, Nov 1, 2022 at 4:40 PM Gretchen LeMay <glemay@cwerksglobal.com> wrote:

> Mary

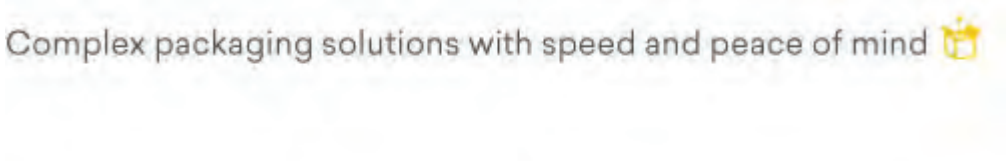
Following up on this email to confirm that you received it. I also left a voicemail on both phone numbers that you provided in system.

Thank you,

Gretchen

**Gretchen LeMay**
Head of People / Corporate Vice President

1470 Brummel Ave,
Elk Grove Village, IL 60007
630-422-3587 *(office)*
creative-werks.com




---

**From:** Gretchen LeMay
**Sent:** Tuesday, November 1, 2022 8:42 AM
**To:** assist2law@gmail.com
**Subject:** Attorney Interview- Tomorrow
**Importance:** High

Mary

Our outside counsel will be interviewing you in person tomorrow to discuss your report. Please find the pertinent information below and confirm back via email that you have received this information.

**Date & Time: Wednesday, November 2 at 10am CST**

**Where: Law Office of Ford Harrison**

**180 N. Stetson Ave**

**Suite 1660**

**Chicago, IL**

**Who: Kimberly Ross**

The law office is in the Prudential Plaza building. You will enter the building on Randolph and take the escalator to the front desk where you will check in and get a pass. You will need your ID.

Please confirm that you have received this email and if you have any further questions.

Thank you,

Gretchen

**M. Madison E-File.zip**
2157K

**Exhibit 21**

Gmail

**Mary Madison <assist2law@gmail.com>**

## Attorney Interview- Tomorrow

**Mary Madison** <assist2law@gmail.com> Wed, Nov 2, 2022 at 2:13 AM
To: Gretchen LeMay <glemay@cwerksglobal.com>

Good day Ms. LeMay

I am in receipt of your 4:40 pm email and voice mail, of November 1, 2022, regarding an interview with the company's outside counsel on November 2, 2022. When you, Wendy and I last spoke on Wednesday, October 26, 2022, you indicated that I was being suspended for the conversation that I had with Mr. Schroder on Friday, October 21, 2022.

When I asked why I was being suspended, you indicated that you conducted an investigation that concluded that the issues raised in the risk assessment that I prepared, as the quality regulatory manager, for Mr. Schroder were totally unfounded.

In seeking to better understand the scope of the investigation, I repeatedly asked what the investigation entailed. Each time, you declined to share any information including what those findings were. It was after those requests that you stated that you reviewed my emails and I had also violated a company policy by allegedly sending company property to an outside email address, as a further reason for my suspension. In seeking further clarification, regarding sending company property to an outside email, I asked you a couple of times what was sent? You stated it was something related to the Dunkaroo's account. To which, I categorically deny such an action. You also cited my assertion in the risk assessment that the company had made false statements as the main contributing factor for my suspension.

In support of my contentions, I offered you a report that underscored issues raised in the risk assessment; which, in my opinion, would have brought clarity to the situation. However, you refused to review it and further suggested that I present it to the outside counsel. As such, the adverse employment decision to discipline me with suspension was made without affording me an opportunity to participate in the investigation.

After careful consideration and my inability to reconcile the purpose for speaking with outside legal counsel, I believe that I too need legal counsel when I speak with the company's outside counsel. In light of the circumstances, the discipline against me suggests, I need legal counsel to protect my interest.

Further, being suspended feels more like a punishment for raising issues relative to non-compliance. In my opinion, this goes against the very spirit of the purported open door policy and transparency mantra of "see something say something" that is touted in this organization. I believe this discipline goes against the purpose for which I was hired.

As a direct result of not understanding this process and my desire to protect my interest and rights, I am exercising my right to have legal counsel present during this interview. Further, you stated that you would be in contact with me within a day or so to arrange this meeting. However, almost a week later contact is made for a next day appointment. Due to this short notice, I will need time to arrange for my counsel's availability for any meeting with the company's outside counsel.

Thank you for your time, consideration and assistance in this matter.

Mary Madison

[Quoted text hidden]

**Exhibit 22**

## Mary Madison: Statement; Risk Analysis and Personnel File Requests

1 message

**Jordan Hoffman** <jthoffmanlaw@gmail.com> Thu, Jan 19, 2023 at 10:09 AM
To: Craig R. Thorstenson <CThorstenson@fordharrison.com>
Bcc: Mary Madison <assist2law@gmail.com>

Good morning, Craig. Please find the referenced documents attached. Thank you.

Jordan

The Law Office of
Jordan T. Hoffman, P.C.
2711 East New York St., Suite 205
Aurora, IL 60502
888.958.4529 Phone and Facsimile
jthoffmanlaw@gmail.com

***"Balancing the Scales of Justice"***

www.attyjthoffman.com

## Mary Madison: Statement; Risk Analysis and Personnel File Requests

1 message

**Craig R. Thorstenson** <CThorstenson@fordharrison.com> Fri, Jan 20, 2023 at 9:53 AM
To: Jordan Hoffman <jthoffmanlaw@gmail.com>

Hi Jordan

I've asked Creative Werks to pull together Madison's personnel file and will provide them to you. She specifically asks for the investigation findings in her request. We will not be providing any investigation report or findings because they are subject to the attorney client privilege.

[Quoted text hidden]

## Mary Madison: Statement; Risk Analysis and Personnel File Requests

1 message

**Jordan Hoffman** <jthoffmanlaw@gmail.com> Fri, Jan 20, 2023 at 10:59 AM
To: Craig R. Thorstenson <CThorstenson@fordharrison.com>

Good morning, Craig. Thank you for your response. Surely, the attorney-client privilege doesn't extend to the in-house communications between the decision makers that are in Ms. Madison's file relative to Creative Werk's preliminary investigation that lead to her suspension.

Jordan

The Law Office of
Jordan T. Hoffman, P.C.
2711 East New York St., Suite 205
Aurora, IL 60502
888.958.4529 Phone and Facsimile
jthoffmanlaw@gmail.com

***"Balancing the Scales of Justice"***

www.attyjthoffman.com



[Quoted text hidden]

**Exhibit 23**

## Mary Madison and Creative Werks

1 message

**Craig R. Thorstenson** <CThorstenson@fordharrison.com> Tue, Mar 7, 2023 at 3:54 PM
To: Jordan Hoffman <jthoffmanlaw@gmail.com>

Hi Jordan,

Thanks for getting back to me. Creative Werks has offered a fair separation package to Ms. Madison and was aware of all the various laws she mentions at the time it made that offer. If she has a specific request she would like Creative Werks to consider, she should make it. Absent a specific offer from Ms. Madison to resolve this dispute, Creative Werks will not increase its offer.

[Quoted text hidden]

## Contact

www.linkedin.com/in/kathyknutsonphd (LinkedIn)

## Top Skills

Food Science
Microbiology
Food Safety

## Languages

Latin (Limited Working)
German (Elementary)

## Certifications

Teaching Certificate - Family and Consumer Science, Foods
Sanitation Manager
Food Safety HACCP Manager
Lead Instructor

## Publications

Hazard Analysis and Critical Control Points (HACCP) for the Cannabis Industry

Knutson KM, Marth EH, Wagner MK. Important milestones in the history of milk pasteurization. Dairy Food Sanit. 1987. 7:459

Overview of the FDA juice HACCP rule

Microbiology 101 Part 1

Juice HACCP Training Curriculum

# Kathy Knutson, Ph.D., PCQI, HACCP-certified

Food and Cannabis Consultant | PCQI Coach & Lead Instructor | Author of "Food Safety Lessons for Cannabis-Infused Edibles" | Chair, Education Committee, National Cannabis Industry Association
Green Bay, Wisconsin, United States

## Summary

If you are in the food or cannabis industry, I want to network with you! I am a microbiologist with expertise in food safety. I travel nationally and globally to consult side-by-side with manufacturers on recall investigations, risk assessments, problem-solving, training, and Food and Drug Administration (FDA) compliance. I trained to be a Lead Instructor with the FDA-recognized curriculum for Preventive Controls Qualified Individuals (PCQIs) in 2016. At last count, I have delivered 40+ PCQI workshops training 500+ PCQIs.

With 35+ years in microbiology and 15 years of full-time teaching, I am passionate about training and can effectively communicate at all levels in an organization from line operator to CEO. I have taught and consulted with companies on laboratory methods, interpretation of lab results, quality assurance, sanitation, environmental monitoring, Standard Operating Procedures (SOPs), Good Manufacturing Practices (GMPs), Hazard Analysis and Critical Control Points (HACCP) and the FDA's Food Safety Modernization Act (FSMA).

When I am not traveling for work, I work remotely from home in Green Bay, Wisconsin, where I live with my husband and an adorable Bernedoodle. In 2019 my two sons both made me Nana.

## Experience

### Kathy Knutson Food Safety Consulting LLC
7 years 8 months

Guest Speaker, Advisory Board Member
March 2022 - Present (1 year 6 months)
Globally

I am available for work as a guest speaker for any level within an organization from line workers to investors. I am available to serve as an external technical resource such as serving on an advisory board. I have been working full-time for over six years as a consultant for the delivery of webinars, creation of documents remotely, and boots-on-the-ground support for food and cannabis-infused edibles manufacturing. I have built a wealth of experience through observation, trouble-shooting, and developing programs to meet FDA compliance.

### Lead Instructor & Preventive Controls Qualified Individual (PCQI)

January 2016 - Present (7 years 8 months)

Nationwide, call 920.309.2412 mobile

As a PCQI myself, I work remotely from home and travel to work on-site as a consultant with facilities in support of action plans to meet the requirements of FSMA or state code. I'm available for project work writing food safety plans with standard operating procedures and forms for documenting them as well as food microbiology, hazard analysis, and Good Manufacturing Practices with subject matter expertise.

I lead a three-day, on-site PCQI training workshop for food company employees as defined and required by FSMA and as recognized by the FDA. I facilitate training sessions and small-group discussions. I received Lead Instructor certification in 2016 from the Food Safety Preventive Controls Alliance with the FDA-recognized curriculum. Individuals completing the workshop receive an endorsed PCQI certificate of participation and recognition. All food companies are now under FDA compliance for the Preventive Controls for Human Food rule.

### NSF International

Independent Contractor

June 2016 - Present (7 years 3 months)

Nationwide

I started with NSF as a Lead Instructor for the FDA Preventive Controls for Human Food rule which requires a Preventive Controls Qualified Individual (PCQI). I have trained PCQIs across the nation. In addition to the PCQI training, I deliver webinars on Food Defense and on Food Allergens. I deliver training on Environmental Monitoring on-site, and NSF is looking to offer this training as a webinar. The webinars are interactive with me through the software and have been very well received.

ImEpik www.imepik.com
Project Manager
October 2018 - Present (4 years 11 months)
I work remotely from home.

ImEpik offers an online, self-paced course to meet the FDA requirement for Preventive Controls Qualified Individual (PCQI). I am updating the curriculum to keep the course current with the FDA rule and guidance, and I am writing a new course for cannabis manufacturers.

EAS Consulting Group, LLC
Independent Contractor
April 2018 - Present (5 years 5 months)
Nationwide

As a contracted consultant, I work with the food and cannabis industries on urgent issues on a project basis. I have reviewed documentation and written reports from home. I have traveled to facilities to conduct a risk assessment of the environment and observe Good Manufacturing Practices (GMPs).

Kornacki Microbiology Solutions, Inc.
Consulting Microbiologist
January 2016 - Present (7 years 8 months)
Nationwide

I joined Dr. Jeff Kornacki in his pursuit of the elusive pathogen in food and manufacturing environments. I investigate the root cause of contamination, research topics of interest within food safety, consult with attorneys and food company clients, write technical reports, and other work in support of the food industry.

Jeff and I, along with CloroDiSys, delivered a three-day workshop in March 2017 and then in February 2018, covering current issues in food safety. The co-sponsored workshop is in Atlanta in February 2019 at the Emory Conference Center. https://foodsafetycon.com/

ConnectFood
Expert Services Team Member & Blogger
August 2012 - Present (11 years 1 month)
Chicago, IL

As a member of the Expert Services Team, I work one on one with professionals in the food industry to write and review their plans remotely. ConnectFood offers an online HACCP and food safety plan builder with

software support for a user-friendly program for creating a flow diagram, hazard analysis, CCPs and preventive controls.

At the ConnectFood website, I post to a food safety blog based on my experience working with industry and as a Lead Instructor for the FDA-recognized curriculum for Preventive Controls Qualified Individuals (PCQI). I monitor industry news and communication from FDA, USDA and CDC for content.

### Northland Laboratories
3 years 6 months

#### Proficiency Program Coordinator
January 2016 - August 2016 (8 months)
Green Bay, Wisconsin Area

#### Food Safety Educator
March 2013 - August 2016 (3 years 6 months)
Northbrook, IL; Green Bay, WI

I delivered workshops to members of the food industry, including lab techs, QA managers, sales, purchasing, production managers, sanitation and product development scientists.

### Notre Dame de la Baie Academy
#### Chemistry Teacher
August 2014 - May 2015 (10 months)
Green Bay, Wisconsin Area

I taught five sections of high school chemistry to juniors.

### Cherney Microbiological Services
#### Project Manager
January 2014 - July 2014 (7 months)
Green Bay, Wisconsin

I managed non-routine testing and project work, evaluated lab instruments and methods and wrote technical reports for clients.

### The Traveling Vineyard
#### Wine Marketing Consultant
May 2012 - December 2013 (1 year 8 months)
Illinois

I hosted in-home wine tasting experiences for wine enthusiasts and their guests.

### Homewood-Flossmoor High School
Culinary Arts Teacher
2008 - 2011 (3 years)
Flossmoor, IL

I taught Culinary Arts with Family and Consumer Science certification.

### Chicago High School for Agricultural Sciences
Food Science Teacher
2005 - 2008 (3 years)
Chicago, IL

I taught Food Science to sophomores, juniors and seniors, where all 600 students were members of the National Future Farmers of America (FFA). I also volunteered as advisor to the sophomore class student organization and coached the dairy product judging team of the National FFA organization at the FFA Dairy Foods Career Development Event (CDE).

### Silliker
Technical Director-Microbiology & Education Consultant
February 1999 - July 2004 (5 years 6 months)
Chicago Heights, Illinois

I served as the in-house technical resource for staff and clients. As part of the management team, I supervised the media prep team and one quality technician.  I was responsible for customer service and assisted with environmental monitoring with clients to determine testing and interpret results. Trained on PCR. When I left, the lab was converting to LIMS. Later in 2003-2004 I returned to create training materials and deliver external workshops.

### IIT, Institute of Food Safety & Health, formerly National Center for Food Safety & Technology
Outreach Manager, Director of Graduate Studies, and Adjunct Professor
January 2000 - May 2003 (3 years 5 months)
Summit, Illinois

Outreach Manager: As part of the management team, I arranged meetings, workshops, and task forces to bring together professionals from industry, government and academia. On a daily basis, I worked with IIT professors and FDA research scientists on food safety issues with Listeria, E. coli O157:H7, sprouts, high pressure procession, ultrapasteurization of dairy fluids, botulinum toxin and mycotoxin. I supervised the technical editor of the newsletter, two administrative assistants and a graphic designer.

I served as event management for an international conference with break-out sessions during the height of concern with acrylamide in processed foods. I created Juice HACCP training materials in cooperation with FDA, industry and academia and arranged and staffed train-the-trainer Juice HACCP workshops across the US. Other responsibilities included designing materials and staffing the expo booth at conferences.

Director of Graduate Studies: I managed the master's degree programs housed in the Summit-Argo campus of IIT and taught Food Microbiology as part of master's degree programs for IIT. I reviewed graduate student applications and research laboratory assignments.

Adjunct Professor: I taught graduate-level Food Microbiology.

### Northeast Wisconsin Technical College

Instructor, Food and Environmental Laboratory Technician Program
August 1992 - January 1999 (6 years 6 months)
Green Bay, Wisconsin Area

I taught a wide range of courses: Laboratory, Principles, Standards and Practices; Laboratory Math and Statistics; Laboratory Quality Assurance/ Quality Control; Food Science; Environmental Science; Sensory Methods; General Microbiology; Food Microbiology; Analytical Chemistry; and Internship.

I worked with local food and environmental labs to meet industry needs in education of lab techs and place graduates in jobs. I ordered supplies, equipment and educational materials.

I served as an active member of professional organizations related to food, environmental and laboratory operations and attended training workshops and conferences to keep current, and was the advisor of the Food and Environmental Laboratory Technician Club.

### Roth Kase AG and USA

Dairy Microbiologist
July 1991 - August 1992 (1 year 2 months)
Monroe, WI

I acquired Gruyere cheese smear cultures from the factories in Switzerland and the growth of the same cultures in Monroe for use on the first Gruyere production in the United States.

### Jefferson Center Dairy
Dairy Microbiologist
January 1991 - June 1991 (6 months)
Juda, WI

Start-up and repair of cheese factory.

### AuroTech Inc.
Dairy Microbiologist
March 1990 - September 1990 (7 months)
Menomonee Falls, WI

While writing my dissertation and as part of the management team for a dairy-based flavor manufacturer, I conducted research on yogurt cultures.

### Merkts Cheese Company
Quality Control Technician
August 1983 - June 1984 (11 months)
Bristol, WI

I performed standard methods for Babcock fat, moisture, acidity, salt, Aerobic Plate Count, Yeast and Mold Count, and Coliform Count.

Note: Merkts Cheese Company is now part of Bel Brands USA.

## Education

### University of Minnesota
Doctor of Philosophy (Ph.D.), Food Science · (1987 - 1991)

### Eastern Illinois University
Teaching Certificate, Family and Consumer Science - Foods · (2009 - 2010)

### University of Wisconsin-Madison
Master of Science (M.S.), Food Science · (1985 - 1986)

### University of Wisconsin-Madison
Bachelor of Science (BS), Bacteriology · (1979 - 1983)

**Exhibit 25**

Gmail

**Mary Madison <assist2law@gmail.com>**

# Response to your Case 317068: Codex Alimentarius [ ref:_00D60KbN0._5003d8nZYuAAM:ref ]

**"FCIC Inquiry" <fcicinquiry@fda.hhs.gov>** <fcicinquiry@fda.hhs.gov> Mon, Jul 24, 2023 at 7:24 AM
To: "assist2law@gmail.com" <assist2law@gmail.com>

This message is being sent in response to the following submitted inquiry:

Can you provide me the statute that uses or references the codex alimentarius standards relative to food safety.

The Food and Drug Administration's (FDA) Food and Cosmetic Information Center (FCIC)/Technical Assistance Network (TAN) has prepared a response for case number 317068.

Response:

Thank you for your inquiry regarding Codex Alimentarius standards. FDA regulations regarding Codex Alimentarius food standards can be found in 21 CFR 130.6.

I hope this is helpful to you.

Thank you for contacting FDA's FCIC/TAN.

View popular Food Safety Modernization Act (FSMA) questions and

answers identified by the Technical Assistance Network (TAN), on our website.

This communication is intended for the exclusive use of the inquirer and does not constitute an advisory opinion (21 CFR 10.85(k)). Also note that this response is not intended to be a comprehensive list of all applicable requirements. Please check FDA's web page (www.fda.gov) regularly for guidance reflecting our current thinking. Additional information on FSMA can be found on FDA's FSMA web page (www.fda.gov/fsma). This communication may contain information that is protected, privileged, or confidential. If you have received it in error, please immediately delete all copies.

**Please do not reply to this email box. If you would like to submit a follow-up question or need clarification to this inquiry, please click here www.fda.gov/fcic and reference this inquiry's case number.

In order to improve our service, we'd like your opinion about your experiences using the FSMA TAN - http://cfsan.force.com/Responsesurvey

EXHIBIT 26

**Mary Madison**

**From:** "FCIC Inquiry" <fcicinquiry@fda.hhs.gov> <fcicinquiry@fda.hhs.gov>
**Sent:** Wednesday, March 26, 2025 1:22 PM
**To:** Mary Madison
**Subject:** Response to your Case 411071: Other [ ref:!00D600KbN0.!500SJ0SjbPwYAJ:ref ]

This message is being sent in response to the following submitted inquiry:

Can you provide the authority that shows that FSMA takes precedence over voluntary certifications such SQF.

The Food and Drug Administration's (FDA) Food and Cosmetic Information Center (FCIC)/Technical Assistance Network (TAN) has prepared a response for case number 411071.

Response:

Thank you for your inquiry. The Food Safety Modernization Act (FSMA) is a Federal law enacted by Congress. Voluntary certifications are not law. FDA-regulated food businesses must comply with all relevant FSMA provisions. FDA does not require compliance with any voluntary certifications.

I hope this information is helpful. You may wish to consult an attorney if you have additional questions about Federal law as it relates to voluntary third-party certifications.

**Exhibit 27**

Catherine Adams Hutt, PhD, RD, CFS
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**MS. MARY MADISON,**
**Plaintiff**

**vs.** **Claim No. 301015087**

**CREATIVE WERKS,**
**Defendant**

# EXPERT REPORT OF CATHERINE ADAMS HUTT, PH.D., R.D., C.F.S.

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## I. SCOPE OF ENGAGEMENT

I have been retained as an expert witness by counsel for the Plaintiff in the above-captioned case to review documents and render an opinion regarding the validity of Ms. Madison's assertions that Creative Werks had significant weaknesses in the regulatory compliance with the requirements of the Food and Drug Administration (FDA), and food safety and quality systems.

In doing so, I have been asked to provide information based on my areas of expertise as an expert in regulatory compliance, food safety, quality systems, and experience as a food safety expert in the food manufacturing industry.

## II. SUMMARY OF OPINIONS

It is my professional opinion that there were significant weaknesses in the regulatory compliance of Creative Werk's food safety systems. There were also significant deficiencies in the company's quality systems that underpin their food safety programs. Third-parties, including FDA and customer Nestle, documented weaknesses and non-conformances with regulatory and customer-contracted standards. As a food safety and quality professional, I find that the relevant programs at Creative Werks lacked the robustness that is standard of care in the food manufacturing industry, including food packaging. Importantly, regulatory food safety

plans were overly generalized and lacked essential elements of the detailed risk assessment that is required by regulation. The most significant evidence that corroborates Ms. Madison's allegations of non-compliance and lack of robustness is the Nestle audit from July 2022.

It is my opinion that Ms. Madison was performing her duties as Quality Regulatory Manager at Creative Werks in calling attention to deficiencies she found in regulatory compliance, food safety, and quality management.

## III. PROFESSIONAL BACKGROUND

I received my BS in Food Science at Pennsylvania State University in 1979, my MS in Food Science & Human Nutrition from Michigan State University in 1981, and my PhD in Food Science from the University of Illinois, Champaign-Urbana in 1986. I have also completed a number of additional quality professional courses, including the Carnegie Mellon University Senior Executive Management Program in 1990; FDA Better Process Control School at Pennsylvania State University in 1978; the ISO 9000 Lead Assessor Program at Chipping Campden, UK in 1992; and the Harvard Kennedy Business School Agribusiness Seminar in 2009.

My professional experience has been in both the public and private sectors. I currently work as a consultant providing advice and guidance on a wide range of food and nutrition topics. I have senior experience in regulatory compliance, food safety, nutrition, health and wellness, quality systems management, supply chain, software solutions for management of quality and product development processes, product development, and business strategy.

I have expertise in the areas of food safety, regulatory matters, quality management, and nutrition. I have led the creation and execution of strategic change designed for business results. My work is at the interface of disciplines for solutions; including food safety, regulation, nutrition, quality, innovation, and food science. I focus on strategic analysis, problem solving and building coalitions designed for results. I have senior executive experience with the manufacturing and food service industries, trade associations, and regulatory agencies in the Federal Government.

I have led quality and food safety programs at H.J. Heinz, Campbell Soup Company, McDonald's Corporation, YUM! Brands, Coors Brewing Company; and the industry trade associations, Grocery Manufacturers of America (GMA) and the International Life Science Institute-Nutrition Foundation (ILSI). In addition, I spearheaded nutrition policy for McDonalds for over two years. I led the development of quality systems for the food sector in the 1990s, integrating the globally recognized blueprint for quality management, ISO 9000, into the food industry. I personally developed World-class quality and food safety programs modeled after ISO 9000 and implemented them in over 100 food manufacturing plants globally with the Campbell Soup Company and over 25 plants in North America for H.J. Heinz. I organized and led quality teams for these two food manufacturers, and worked hands-on with operations and Corporate leadership to ingrain the tools and culture of quality management and food safety into these

Fortune 200 companies. I have also worked in food factories with quality and operations teams to solve quality and food safety problems, and developed infrastructure for consistently effective quality and food safety functions.

While at H.J. Heinz, I introduced and delivered a software system for product lifecycle management (PLM). I conceived of the idea with a software architect at Prodika, and we built the PLM software from the ground up over a two-year period of time. The PLM tool enabled H.J. Heinz to accelerate innovation by enabling it to create, manage and collaborate on critical information related to product design, development and introduction, global product specifications, and packaging. The system, called VIPER (Vendor Improvement and Product Enhancement and Research), streamlined product development operations across the enterprise and with supply chain. VIPER reduced time-to-market for new products; optimized supplier relationships; managed quality, food safety and regulatory processes; reduced costs of goods sold; and optimized return on R&D and new product investments. It provided improved visibility and collaboration between sales, marketing, executive management, R&D, sourcing, suppliers, partners and customers. Ultimately, Prodika was acquired by Agile, who was later acquired by Oracle; the PLM tool remains as Oracle's PLM Cloud offering today with multiple global customers.

I led quality and food safety for two of the largest food service companies, McDonald's Corporation and YUM! Brands (then Tricon Restaurants). While there, I developed and led restaurant food safety programs and led quality and food safety with food suppliers, working with the Supply Chain and Purchasing teams. At McDonald's, I was a member of the Global Supply Chain Leadership team, leading quality and food safety initiatives across the global McDonald's system and with all its suppliers. I developed quality leadership infrastructure in for the global organization and worked on problem-solving with key ingredient suppliers. I introduced the PLM software developed at H.J. Heinz into the McDonald's system; and led its application for menu item development, menu management, and supplier management across the global organization. I also led nutrition strategy for global McDonald's, working with global policy makers and internal leadership; I brought change to the menu – including the introduction of a smaller serving of French fries (3.5 oz) with apples for the Happy Meal designed for children. This change represented the first time a new size of French fries had been added to the McDonald's menu in 55 years.

I also held a leadership position at the Federal regulatory agency for meat and poultry food safety, the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS). I was the youngest member of USDA's Senior Executive Service (SES), becoming Assistant Administrator of FSIS at the age of 33. There, I led the global development of the food safety management system, Hazard Analysis and Critical Control Point (HACCP) system as it currently exists, and that has become the method by which all food safety is regulated around the World. I chaired global working groups within the Codex Alimentarius Commission that developed HACCP, and led its integration into U.S. regulatory systems. Codex is the global international authoritative body for food and food safety standards, and I served as delegate for the United States on the Food Hygiene Committee and the Committee on Import Export Certifications. I

testified before the U.S. Congress nine times as Federal regulatory agency representative. I also drafted the initial proposal for international recognition of food safety, plant health, and animal health standards for the Uruguay Round of the General Agreements on Tariffs and Trade (GATT) rules on agriculture; and supported its introduction on the floor of the GATT with the U.S. Chief Negotiator and Ambassador.

I became a consultant in 2008 and lead a consulting firm, RdR Solutions. I am also Chief Science and Regulatory Officer for Sloan Trends, a company providing strategic business solutions based on consumer behavior and trends for industry leading retailers, food manufacturers, and food service organizations. In my role with Sloan Trends, I integrate my knowledge and experience in nutrition science, quality systems, and regulatory compliance to advise businesses on strategic direction in the health and wellness sector. Additionally, I have co-authored a bi-monthly article on consumer trends in *Nutraceuticals World*.

As a consultant, I routinely work on issues regarding food safety, regulatory compliance, quality, nutrition, and crisis management. I have been recognized by leadership teams and by my peers as a strategic visionary with strong business orientation and acumen, an innovative thinker, a decisive leader, and a demanding professional with extraordinary integrity and strong people skills.

I also have received several honors and certifications, including:

- Graduation from Pennsylvania State University with Highest Distinction (First in Class) (1979) Inspections (cdpehs.com)
- US Federal Government, Senior Executive Service (inducted 1990)
- Distinguished Alumnus, Pennsylvania State University College of Agriculture (1995)
- Fellow, Pennsylvania State University (2008)
- Fellow, Institute of Food Technologists (2009)
- Member, Cosmos Club (inducted 2011)
- Registered Dietitian
- Certified Food Scientist

I am a certified Registered Dietitian through the Commission on Dietetic Registration and have been Active status since 1986.

A copy of my Curriculum Vitae, which includes a list of publications I have authored is attached in Appendix A. I have served as an expert in 56 litigations in the U.S. since 2010. A complete list of these engagements is included in my Curriculum Vitae. I have testified as an expert at a deposition and trial 23 times.

I reside at 4568 Elm Bottom Circle in Aubrey, Texas 76227 and am married to Peter Barton Hutt.

## IV. **Overview**

Ms. Madison was employed at Creative Werks as Quality Regulatory Manager in September 2022 and was suspended on October 26, 2022. During her employment in a regulatory compliance role, she observed deficiencies in FDA requirements for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Foods, 21 CFR Part 117.1 – 117.475. She also observed deficiencies in other food safety and quality management programs that are standard practice within the food manufacturing and packaging industry. Deficiencies included a lack of rigor in requisite food safety plans, lack of sensitivity to customer requirements, and lack of sense of urgency is response to regulatory/food safety issues and customer complaints.

My understanding is that Ms. Madison felt it was her responsibility to identify these non-conformances and seek to remedy them. It appeared that she had difficulty in enlightening Creative Werk's management that deficiencies and non-conformances existed, and she resorted to extensive documentation of the shortcomings with recommendations for improvements, including Regulatory Business Problem, October 20, 2022 and Legal Analysis of Regulatory Business Problem, November 12, 2022. While Ms. Madison's approach was intensive, her conclusions were largely correct and corrective actions were required in the planning, documentation, and execution of required elements for regulatory compliance and customer satisfaction.

Based on my experience, it is my opinion that Creative Werks considered their role as a co-packer of previously manufactured products to be a low-risk process and felt it appropriate to develop generic food safety plans for processes, despite the possibility that the products being packaged posed a variety of different risk levels. The fact that regulatory inspections did not cite deficiencies in food safety plans that they did not verify, and did not issue Form 483s does not indicate that all required elements of 21 CFR Part 117 were in compliance. Most notable in my opinion, is the extensive audit with findings by customer Nestle. I have known Nestle quality teams and their performance for four decades. In my experience, Nestle audits are thorough and performed by well-trained auditors knowledgeable of regulatory compliance and the food safety and quality standards of Nestle. The extensive findings cited in their audit of July 2022 of major and minor consequence document an accurate assessment of the systems in place at Creative Werks at the time, that were further identified and documented by Ms. Madison in October and November of that year.

Dr. Knutson's assessment in her expert report focused on the inflammatory language and legal analysis contained in Ms. Madison's documents. In doing so, it is my opinion that Dr. Knutson overlooked the relevant points that there were indeed deficiencies in the processes and documentation for regulatory compliance and customer satisfaction at Creative Werks in the Fall of 2022.

## V. Creative Werks Had Deficiencies in Their Food Safety Programs that Included Regulatory Non-compliances

Notwithstanding Ms. Madison's observations and reports, third-party audits revealed deficiencies in Creative Werks' food safety plans that included major nonconformances with customer requirements and regulatory violations. Nestle conducted an audit of the Bartlett Creative Werks facility in July 2022.[1] The audit findings were reported for the required elements of the Nestle food safety and quality management standards that are aligned with regulatory requirements. Their findings included two major and one minor deficiencies for the section on HACCP, which included food safety plans as required by 21 CFR Part 117.

The Nestle auditor documented that Creative Werks' ingredient risk assessment, as required by Nestle and FDA, was deficient.

The requirements of 21 CFR Part 117.130 are described below, and include that a hazard analysis be performed for reasonably foreseeable hazards.

**§ 117.130 Hazard analysis.**

(a) ***Requirement for a hazard analysis.***

(1) You must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control.

(2) The hazard analysis must be written regardless of its outcome.

(b) ***Hazard identification.*** The hazard identification must consider:

(1) Known or reasonably foreseeable hazards that include:

(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;

(ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and

(iii) Physical hazards (such as stones, glass, and metal fragments); and

(2) Known or reasonably foreseeable hazards that may be present in the food for any of the following reasons:

(i) The hazard occurs naturally;

(ii) The hazard may be unintentionally introduced; or

(iii) The hazard may be intentionally introduced for purposes of economic gain.

1 Exhibit 2, Creative Werks Risk Analysis with Statutes, 12.15.22 file

As part of the hazard analysis, a risk assessment is required for ingredients and the process used in production.[2] This fact is counter to the Declaration of Dr. Kathy Knutson, who stated that "FSPs are written based on process steps, not ingredients."[3]

(c) ***Hazard evaluation.***

(1)

(i) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

(ii) The hazard evaluation required by paragraph (c)(1)(i) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

(2) The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:

(i) The formulation of the food;

(ii) The condition, function, and design of the facility and equipment;

(iii) Raw materials and other ingredients;

(iv) Transportation practices;

(v) Manufacturing/processing procedures;

(vi) Packaging activities and labeling activities;

(vii) Storage and distribution;

(viii) Intended or reasonably foreseeable use;

(ix) Sanitation, including employee hygiene; and

(x) Any other relevant factors, such as the temporal (*e.g.*, weather-related) nature of some hazards (*e.g.*, levels of some natural toxins).

The Nestle audit found that Creative Werks' food safety plan included an ingredient risk assessment document, albeit at a high-level grouping for ingredients; but specifically called out that no risk assessment, i.e., severity/likelihood analysis, had been performed. The corrective

2 21 CFR Part 117.130 (c) (2) (iii).

3 Declaration of Dr. Kathy Knutson, Item #37, p. 11 of 17.

action included that the food safety plans will be written to include severity and likelihood risk assessment as part of each of the plans. Creative Werks described their rationale for the omission as follows: the "Client…have instituted policies around Biological and Chemical concerns with their foods manufacturers which we verify through our Auto Hold/COA process." However, Nestle notes, correctly so, that this statement/position "does not negate the site's responsibility to evaluate the risks of the site's incoming materials."

The second Major non-compliance in this section of the Nestle audit found that the ingredient risk assessment was not included in the annual review of the Packaging Food Safety Plan and that no change control was evident. The corrective action was that the ingredient risk assessment was to be embedded into the food safety plan so it would then become part of the annual plan review.

That the FDA audits of the Elk Grove and Bartlett facilities did not include regulatory violations for the food safety plans does not convey that they were compliant. For both FDA audits of the facilities, the FDA inspector described the audit that did not include review or verification of food safety plans. The Bartlett facility inspection was documented as focused on: "Sanitary Transport, Sanitation, Raw Materials, Customer Complaints, Pest Control, Quality Control, Sales, Production, Purchasing, Recordkeeping, and Employee Training."[4] The report noted that "Time did not permit me to verify the firm's entire food safety plan during the inspection" and noted that the only process preventive control was x-ray equipment.[5] Similarly, the FDA inspection of the Elk Grove Village facility focused on "Sanitary Transport, Sanitation, Raw Materials, Customer Complaints, Pest Control, Quality Control, Sales, Production, Purchasing, Recordkeeping, and Employee Training".[6] Food safety plans were not reviewed nor verified by the FDA inspector.

Ms. Madison includes these two Major Non-conformances identified in the Nestle audit in her analysis entitled, Regulatory Business Problem[7], as Exhibit B. She includes her comments made directly on the Dunkaroos Food Safety Plan contained in this document that the hazard analysis does not comply with 21 CFR Part 117.130, which is the same conclusion as the Nestle auditor for reasons stated above. My professional opinion is that both the Nestle auditor and Ms. Madison were correct in their analyses and statements. Similarly, I disagree with Dr, Knutson's Declaration that Creative Werks' food safety plans were compliant with regulations.[8]

## VI. Creative Werks Had Deficiencies in Their Allergen Control Program

4 FDA Inspection, Bartlett, IL facility, FEI 3011417063, Sept 28-29, 202, p. 3 of 17.

5 *Id*, p. 11 of 17.

6 FDA Inspection, Elk Grove Village facility, FEI 3010131930, July 14-15, 2020, p. 2 of 14.

7 M. Madison, Regulatory Business Problem, October 20, 2022.

8 Declaration of Dr. Kathy Knutson, #5, #10, #36.

The Nestle audit documented that allergen management was not in compliance with the Nestle requirements. First, no allergen matrix was not in place that controlled and communicated which allergens could be run on which line and when. While this standard for an allergen matrix is a Nestle requirement, there are regulatory requirements that also mandate robust allergen controls as part of Preventive Controls that are required in Food Safety Plans.[9] The allergen matrix required by Nestle is a method to control and communicate the presence of and transfer of allergens during production runs. The Nestle audit identified that software existed that was intended to control allergens on production lines, and that there were deficiencies in allergen cleaning on a particular line. The corrective action was that an allergen matrix will be developed detailing which "allergens/clients are approved to run on each of the production lines".[10]

It is clear that the Nestle auditor felt that allergen control was lacking and cross-contamination was a risk, or else this audit finding, classified as Major, would not have been documented as such. Allergen Controls are part of the required elements for a Food Safety Plan as part of Preventive Controls. Preventive Controls are required in 21 CFR Part 117.135 for Process Control, Allergen Controls, Sanitation Controls, Supply-chain Controls, Recall Controls, and Other Controls including training and current good manufacturing practices (cGMPs). The Preventive Control requirements for food allergens is described below:[11]

> (2) ***Food allergen controls.*** Food allergen controls include procedures, practices, and processes to control food allergens. Food allergen controls must include those procedures, practices, and processes employed for:
>
> (i) Ensuring protection of food from allergen cross-contact, including during storage, handling, and use; and
>
> (ii) Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

The second Major finding in the Nestle audit was a repeat finding that Creative Werks had no annual verification for allergen control on all lines and records of verification were difficult to find [12]. These findings are evidence that there is a lack of rigor for the regulatory[13] and customer requirement[14] for allergen management at Creative Werks.

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9 21 CFR Part 117.135 (c) (2) (i) and (ii).

10 Nestle audit, July 2022.

11 21 CFR Part 117.135.

12 Nestle audit, July 2022.

13 21 CFR Part 117.135 (c) (2).

14 Nestle audit, July 2022.

In Dr. Knutson's Declaration, she states that Ms. Madison's marking that the Allergen Preventive Control step in the Dunkaroos Food Safety Plan is "incomplete/non-complaint" is incorrect, and that "the required information is on the next page".[15] The next page of the plan contains the Sanitation Preventive Controls, which is intended for "environmental pathogens" with no mention of allergens. The next page also contains the procedure for "Environmental Monitoring for Sanitation Prevention Control Verification". Again, there is no mention of allergen cleaning or control, and the steps to prevent and verify allergen cross-contamination are not different than that required for pathogen control and verification.

Further, Dr. Knutson states in her Declaration that Ms. Madison's statement that cGMPs that "relates to Processes and Controls and are missing from the above matrix" is "false and misleading".[16] Dr. Knutson's rationale is stated as: "GMPs are not part of the FSP" (food safety plan). The fact is that cGMPs are part of the Food Safety Plan, as stated in "Other Controls" required in 21 CFR Part 117.135 (see above paragraph).

The fact is that Creative Werks had deficiencies in their Allergen Control Program that were identified by Nestle as a external auditor. Ms. Madison called out non-conformances with the Nestle standards and regulatory violations. Dr. Knutson's negative assessment of her findings is simply incorrect.

**VII. Creative Werks Had Deficiencies in Their Production Controls**

The Nestle audit of the Creative Werks facility showed Major deficiencies in production controls that relate to food safety. These deficiencies included acceptance of a Certificate of Analysis (COA) that did not contain all the required microbiological food safety criteria. The COA was missing information about yeasts and molds, *E. coli* and coliforms, important indicators of fecal contamination and shelf-life. There was also a finding of an unapproved vendor and another finding of improper finished product release procedures.[17] While these findings are not necessarily regulatory violations, they are indicative of failures in the food safety program that can lead to adulterated product in the marketplace. They are also customer-specified requirements that Creative Werks agreed to implement and maintain as part of their business with Nestle. Failures in these production controls at Creative Werks reflects a lack of diligence in adherence to quality and food safety processes that are the standard of care in the industry, and a lack of sensitivity to customer requirements.

Ms. Madison included compliance to customer requirements in her report. Dr. Knutson takes exception to Ms. Madison's consideration of customer requirements, stating in item #19 of her Declaration, "I disagree. Customers do not dictate food safety, and quality parameters are managed separately from food safety."[18] As an experienced food safety and quality professional with over 40 years experience in the industry, I disagree with Dr. Knutson on two

15 Declaration of Dr. Knutson, p.5.

16 *Id*.

17 Nestle audit, July 2022.

points. One, customers routinely dictate adherence to their own standards, which include matters relating to food safety. Their standards also comply with regulatory requirements, but often customers add specific food safety criteria above and beyond regulatory compliance. For example, microbiological criteria as part of a product or ingredient specification may include aspects in addition to the company's standards, but the customer has deemed it important for their product and brand; and co-packers such as Creative Werks agree to comply as a basis for doing business. Second, it is a fact that quality procedures routinely underpin and support compliance to food safety requirements. Quality systems are in place to ensure that food safety practices do not erode over time.

I am confused by Dr. Knutson's statement since it is unclear what customer requirements she believes are quality parameters unrelated to food safety. The Nestle audit called out production failures including incomplete COA received and accepted, an unapproved vendor used, and failure of finished product release procedures. I regard all these matters as important to food safety, and quality procedures are in place to make sure the food safety practices are upheld.

Dr. Knutson states in her Declaration in paragraph #32 that it is Creative Werk's responsibility to verify the control of hazards by the supplier through, for example, review of a COA.[19] However, Creative Werks reviewed and accepted a COA that lacked three of the six required microbiological criteria for acceptance.[20]

Further, in Dr. Knutson's Declaration paragraph #33, she contends that Creative Werks does not need to be performing any verification activities.[21] She cites Creative Werks Food Safety Plan for Dunkaroos, which includes a statement, "Supply Chain Preventive Controls are thereby managed by General Mills and hazard control verification owned by General Mills." [22] The fact is that this statement by Creative Werks is wrong and Dr. Knutson citing it as defense for the lack of verification activities by Creative Werks is also wrong. Supplier Controls are part of the Preventive Control dictated by 21 CFR Part 117.135. Supplier Controls are required as part of Food Safety Plans. Creative Werks cannot make a declaration that Supplier Controls are managed by their customer, and they do not need to apply Supplier Controls. Saying it does not make it so.

**VIII. Creative Werks Had Deficiencies in Non-conforming Product Control and Systemic Compliance with Customer Requirements**

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18 Declaration of Dr. Kathy Knutson, #19.

19 *Id*., #32.

20 Nestle audit, July 2022.

21 Declaration of Dr. Kathy Knutson, #33.

22 *Id*.

The Nestle audit identified instances where Creative Werks released Nestle non-conforming product without approval from Nestle. The Nestle standard used for the audit clearly indicates that Nestle expected to be informed in the event that non-conforming product was being considered for release from manufacturing.[23] The audit criteria states that "Release decision is owned by Nestle Quality." Creative Werks failed to communicate with Nestle regarding two situations where products did not comply with net content requirements, and another where an expired peanut ingredient was on hold and under review without informing Nestle. While these are clearly customer requirements and not necessarily regulatory violations *per se*, a product released that did not comply with net content requirements could be a regulatory violation and Nestle indicated that they wanted to control the decision.

It is my opinion that these two violations found in an audit indicates that there is a systematic and systemic disregard for customer requirements at Creative Werks. Ms. Madison called out noncompliances at Creative Werks that indicated to her "systematic and systemic issues". In my experience, a company that overrides a customer's request for involvement in decision making shows a disregard for that customer, and reflects the skewed culture of the company. Ms. Madison cited in her report that she believed Creative Werks suffered from a culture that lacked transparency[24], and Nestle's observations in their audit of July 2022 verify that her report was not incorrect.

## IX. Creative Werks Had Deficiencies in Change Management Process

Creative Werk's customer, Nestle, required that contract manufacturers have a management of change process in place to manage changes to products, processes, equipment, and workplace that affect foods safety and the regulatory requirement of compliance for 21 CFR Part 117, Preventive Controls. The Nestle audit in July 2022 documented that Creative Werks had a "insufficient/ineffective" management of change process in place.[25] The auditor noted that there was no evidence of a management of change process for internally-initiated changes to the product or facility, and no process for changes initiated by customers.

The management of change process is core to the architecture of food safety and quality processes. Food safety risks are encountered when changes occur, for example, product formulation, ingredients, packaging, equipment, or facility maintenance/construction. It is standard industry practice that each change event should trigger a review to assess whether changes are required in allergen control or labeling, sanitation, or preventive maintenance, for example. The Nestle finding documented that Creative Werks lacked such a process, making the operation vulnerable to food safety risks that were not being anticipated and not managed. The Nestle audit documented an example where changes in their product's graphics/item formulation were modified, but there was no review of primary packaging to determine if

23 Nestle audit, July 2022.

24 M Madison Report NAME and PAGE

25 Nestle audit, July 2022.

allergen updates were needed.[26] While a management of change process is not a direct regulatory requirement, it was a customer standard for Creative Werks. Importantly, it made the operation susceptible to mistakes that can create food safety hazards and regulatory violations.

## X. Creative Werks Had Deficiencies in cGMP Requirements in Violation of 21 CRF Part 117

Both the Nestle audit and the FDA inspections note deficiencies in Creative Werk's cGMP compliance.

Nestle documented **repeat violations** that dock door maintenance was insufficient, resulting in dock door seals that were in state of disrepair. They noted:

> *"BEN – Door 11 had a missing window and leveler that was broken; Door 8 was missing dock leveler brushes; Door 7 leveler brushes deteriorated; Door 10 was left open 2 inches; Door 6 and others nearby – water ingress when raining; Evidence of air gaps observed in some cases when trailers are backed to the door."*

These same violations were also detailed in the FDA inspection report for the Elk Grove Village facility[27]:

> *"I observed the west dock doors as follows: 5, 7, 12, 15, and 16 all had light seeping inward. I also observed the external southeast dock doors had light seeping inward."*

Dock door closure violations were also noted in the FDA inspection of the Bartlett facility[28]:

> *"I observed light seeping in through dock door #5 during the walk-through."*

It is clear that Creative Werks failed to correct the dock door maintenance problems following the prior year audit by Nestle, and these violations were noted in regulatory inspections of two Creative Werks facilities.

Other GMP/sanitation violations were also noted in each of the regulatory inspections for Elk Grove Village and Bartlett facilities. In the Bartlett facility, a production employee was using a towel to clean equipment and touching the floor for balance, then alternating the hand that had touched to floor to the towel for cleaning equipment[29], effectively cleaning the equipment with whatever was on the floor. In the Elk Grove Village facility, an employee was observed on

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26 Nestle audit, July 2022.

27 FDA Inspection, Elk Grove Village facility, July 14-15, 2022, p.13.

28 FDA Inspection, Bartlett, September 28-29, 2022, p. 15.

29 FDA Inspection, Bartlett, September 28-29, 2022, p. 15.

a production line doing a similar action, touching the floor with a gloved hand then touching food contact surfaces with the gloved hand that had touched the floor.[30]

Other concerns were noted in the FDA inspections that included deficiencies in training recordkeeping[31] [32], pest control[33] [34], handwashing stations that were not prevalent in critical production areas with exposed products[35], and a consumer complaint response that "should have had a faster response"[36].

Both inspections included notations by the inspector that concerns were identified for management during the inspection, but no corrections made.[37] Observations and concerns were shared with management during the inspection regarding gaps at the dock doors, but there was no response from management at the time regarding corrective actions.[38]

It has been my experience and is standard industry practice that when FDA inspectors or other auditors make observations to management, every effort is made to provide corrective action and a remedy on the spot. Failure to respond to an inspector's comments is a reflection of a culture that lacks urgency and priority for regulatory compliance.

## XI. Assessment of Specific Items in Dr. Knutson's Declaration

Dr. Knutson's Declaration identifies multiple statements and actions by Ms. Madison which she states are false, misleading, not truthful, or confusing. In addition to the arguments I have made in the above sections, I address specific declarations made by Dr. Knutson and identify why Ms. Madison's assertions in her report were indeed reasonable.

(a) Declaration: *Food Safety Plans are Compliant*[39] – This is Not Correct

Ms. Madison correctly stated that "there has been an improper interpretation, analysis, and application of the relevant statutes, standards, and regulation relative to the business unit's

30 FDA Inspection, Elk Grove Village, July 14-15, 2022, p. 12.

31 FDA Inspection, Bartlett, September 28-29, 2022, p. 15.

32 FDA Inspection, Bartlett, September 28-29, 2022, p. 9.

33 FDA Inspection, Bartlett, September 28-29, 2022, p. 15.

34 FDA Inspection, Elk Grove Village, July 14-15, 2022., p. 13.

35 FDA Inspection, Elk Grove Village, July 14-15, 2022, p. 12.

36 FDA Inspection, Bartlett, September 28-29, 2022, p. 15.

37 FDA Inspection, Elk Grove Village, July 14-15, 2022, p. 8.

38 FDA Inspection, Bartlett, September 28-29, 2022, p.10.

39 Declaration of Dr. Kathy Knutson, p.5.

objectives in manufacturing, co-packing and compliance." The Nestle audit, an external review of the food safety plans and their compliance, found them deficient in that they lacked an adequate risk assessment of severity and likelihood of the hazards. An ingredient risk assessment is required according to 21 CFR Part 117.130 (c) (2) (iii). The Creative Werks' Food Safety Plans contained a high-level ingredient assessment but lacked a rigorous risk assessment with severity and likelihood of an adverse event considered, according to Nestle auditors. Creative Werk's assertion that food safety plans are adequate because the responsibility for hazard analysis and controls belongs to the product manufacturer is not correct or appropriate, and each facility is required to adequately assess and control hazards under 21 CFR Part 117.

In addition, required Allergen Controls were considered insufficient by the Nestle auditor.

Dr. Knutson's statement in her Declaration that "Audits carry no force of law"[40] is completely irrelevant. The salient point is that the Nestle audit was an in-depth review of the Creative Werks manufacturing site and weaknesses and regulatory deficiencies were revealed. The two FDA inspections in 2022 did not review food safety plans for either the Bartlett or Elk Grove Village facilities.

(b) Declaration: *There Was No Evidence that Creative Werks Failed to Act Swiftly in Work Toward Compliance with Regulatory Requirements* – This is Not Correct

Repeat violations were documented by the FDA inspector in cGMPs regarding dock door integrity in both the Bartlett and Elk Grove Village facilities. Dock door gaps and inadequate maintenance were also documented in the Nestle audit as a repeat violation. The FDA inspector noted that a consumer complaint should have had a faster response. The FDA inspector noted in their reports that observations were identified to Creative Werk's management during the walk-through with no corrective action.

Dr. Knutson's declaration that Ms. Madison's statement regarding "no evidence that a formidable plan of action is in place or being developed to remediate the noncompliance and outstanding compliance issues"[41] is incorrect on a similar basis as stated above.

(c) Declaration: *Ms. Madison's Recommendation for Contract Management "Does Not Make Sense"*[42] – This is Incorrect

That Ms. Madison would include a recommendation that Creative Werks address contract management is clear in the sense that their role is as co-packer. Customer expectations and standards are declared within the context of a business contract and this contract's contents are well within the scope of the regulatory and quality/food safety representative, in my experience.

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40 Declaration of Dr. Kathy Knutson, p.5.

41 Declaration of Dr. Kathy Knutson, p.6.

42 Declaration of Dr. Kathy Knutson, p.7.

(d) Declaration: *There is "No Evidence of a Company in Crisis"*[43] – This is Incorrect

As an experienced quality and food safety professional, I understand the term "crisis" to be a relative one. I have called attention to situations in my roles in leadership that I considered crises. A company in crisis to me was a company with multiple non-conformances to regulations and customer expectations - without an urgent plan to remedy them. FDA issuance of Form 483s are not required to call out an alarm and I regard Ms. Madison's assertions regarding a crisis situation appropriate.

(e) Declaration: *The Nature of Creative Werks' Business Was "Low-Risk" and Suppliers Control Hazards"*[44] – This is Incorrect and Misled

Dr. Knutson appears to make this declaration as a rationale for lack of robust food safety plans that meet the requirements of 21 CFR Part 117. The fact is that suppliers of products to Creative Werks were required to control hazards in their manufacturing process and facility, in accordance with the regulations – just as was Creative Werks.

The level of risk in manufacturing packaged final products may be of lower risk than their production using raw ingredients, but the required process is to document the lower risk through a thorough risk assessment and safeguard the products during packaging. The level of risk in the process does not obviate the need to comply with regulatory requirements. Ms. Madison's report recognizes that Creative Werk's had the responsibility to document and implement adequate food safety plans and processes, and work appropriately in their context as a co-packer.

(f) Declaration: *Ms. Madison's Actions Lacked Teamwork and She Worked Alone* [45]– These Assertions Are Out of Context

Dr. Knutson is critical of Ms. Madison for acting alone in writing her report. She also states for reference that her training as PCQI should have taught her to work as a team. Dr. Knutson is correct in that the development of food safety plans in a facility is a multi-disciplinary team effort. However, Ms. Madison's assertions are made regarding deficiencies in the management and planning of the Creative Werks' processes and facilities, and not the development of food safety plans. Dr. Knutson's criticism of Ms. Madison's actions in this matter are made out of the appropriate context and is misled.

(g) Declaration: *It is an "Important Point… That Ms. Madison Wore a Dress and Earrings to Work*" – This Criticism is Unimportant, Unmerited, and Reprehensible

43 Declaration of Dr. Kathy Knutson, p.7.

44 Declaration of Dr. Kathy Knutson, p.8.

45 Declaration of Dr. Kathy Knutson, p.9.

As a quality and food safety professional, I find this allegation inappropriate and completely unnecessary. In fact, it is offensive.

Dr. Knutson states that "Wearing a dress and earrings to work is indicative of her lack of understanding of common food safety practices."[46] What Ms. Madison wore to work is unimportant; in fact, I believe that Ms. Madison's wardrobe choices demonstrated that she was a professional in the workplace and worked to present a quality impression. It is easy to bring a set of appropriate pants, no-button shirt, and flat safety shoes to work to change into in order to go to the production floor for her work. There is no indication that Ms. Madison inappropriately wore a dress and jewelry on the production floor, which would be a violation of cGMPs. There is no indication in Dr. Knutson's observation that Ms. Madison was unaware or failed to comply with proper attire on the production floor.

(h) Declaration: "*Rarely Does an FDA Inspection End Without a Form 483*"[47] – This is Incorrect

In my four decades of experience with FDA-regulated facilities, I disagree vehemently with this declaration. It is simply incorrect. The issuance of a Form 483 is a significant event and is completed when an FDA inspector, or a state inspector performing inspections under contract with FDA, observes "conditions or practices observed would indicate that any food, drug, device or cosmetic has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health."[48]

It is my experience that the issuance of a Form 483 as part of an FDA inspection is not a common event, and it is certainly not my experience that rarely does an FDA inspection end without a Form 483. According to FDA, there were 2399 Form 483s issued for food between October 2, 2021 and September 30, 2022. A total of 727 of these were for violations of the Foreign Supplier Verification Program (FSVP)[49], meaning 1672 were issued for other regulatory violations. In 2021, there were a total of 10,666 inspections conducted by FDA and state-contracted officials[50], which is less than in previous years in large part due to COVID restrictions. In the 2021 period, Form 483s were issued in approximately 15% of inspections not including FSVP issues, and approximately 22% of inspections overall. In the relevant time period, even

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46 Declaration of Dr. Kathy Knutson, p.9.

47 Declaration of Dr. Kathy Knutson, p.10.

48 FDA Form 483 Frequently Asked Questions, FDA Form 483 Frequently Asked Questions | FDA, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions.

49 FDA Inspectional Observations, Inspection_Observations_FY22.xlsx (live.com), https://view,officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.fda.gov%2Fmedia%2F163420%2Fdownload%3Fattachment&wdorigin=BROWSELINK.

50 Environmental Working Group, FDA food safety inspections plummet, despite congressional mandate | Environmental Working Group (ewg.org), https://www.ewg.org/news-insights/news/2022/05/fda-safety-inspectiosn-pluimmet-despite -congressional-mandate.

considering fewer FDA inspections in and after the COVID timeframe, Form 483s were issued in about one inspection out of five. It is incorrect for Dr. Knutson to declare that it is rare for an FDA inspection to end without a Form 483 issued.

It is also true that FDA did not review Creative Werks' Food Safety Plans, which should have resulted in the issuance of a Form 483.

(i) Declaration: "*Quality Issues Are Managed Separately from Food Safety*"[51] – This is Incorrect

As an experienced quality and food safety professional, it is my opinion that Dr. Knutson's declaration is incorrect and misled. Ms. Madison appropriately states in her report that "the lack of food safety plans underscored quality issues". Dr. Knutson's further states that FDA is "not concerned about quality issues", which is simply not true.

It is my experience that quality processes ensure that food safety is implemented and maintained. I have supported the installation of over 150 quality management systems that supported effective HACCP plans in the 1990s and early 2000s. There are many aspects of quality performance, and some are more closely related to product and customer expectations than food safety, e.g., product and customer specification compliance and control of variation. Other quality parameters include cGMPs, such as personal hygiene and facility maintenance, which are part of regulatory requirements and compliance.

(j) Declaration: *Creative Werks is Responsible for Control of Hazards Including "Cross-contact of Allergens or Shared Equipment*" – This is Correct; and *She Failed to Identify Documented Weaknesses in Creative Werks Allergen Controls*

Dr. Knutson reviewed the Packaging Food Safety Plan and correctly stated that it was Creative Werks' responsibility to control cross-contact of allergens. She failed to identify that the Nestle audit included Major findings of deficiencies in Creative Werks' Allergen Controls, as required by 21 CFR Part 117.135.

## XII. Conclusions

It is my professional opinion, to a reasonable degree of scientific certainty and based on my education, training, Ms. Madison was performing her duties as Quality Regulatory Manager at Creative Werks when she identified weaknesses in their food safety and quality programs, and documented regulatory violations with 21 CFR art 117. Regulatory violations were identified in the Nestle customer audit of July 2022, and cGMP weaknesses were documented by FDA inspectors in 2022 at both the Elk Gove Village and Bartlett Creative Werks facilities.

51 Declaration of Dr. Kathy Knutson, p. 11.

Dr. Kathy Knutson's Declaration includes inaccuracies and misleading statements regarding Ms. Madison's assertions that regulatory, food safety, and quality performance at Creative Werks should be improved and changes made in a timely manner. Creative Werks was not performing in a manner consistent with industry standards.

I reserve the right to amend or supplement my opinion and conclusions based on receipt of additional documents and/or new information.

**XIII. Data and Information Considered**

I have been provided with and reviewed document files for this case, including:

Creative Werks Risk Analysis with Statute 12.15.2022
Madison and Expert Reports Creative Werks
Mary Madison Resume _2022
Madison Review of CV
Overview CW 08.5.23
Exhibit 1-14 CAH

I reviewed websites for the FDA including Inspection Observations, Form 483 Frequently Asked Questions, and Form 483 database for foods.

I also reviewed an article posted by the Environmental Working Group.

I reviewed 21 CFR Part 117 and subparts.

Signed,

Catherine Adams Hutt, PhD, RD, CFS
August 14, 2023

**Appendix A.**

**CATHERINE ADAMS HUTT, Ph.D., R.D., C.F.S.**

**Address:** 4568 Elm Bottom Circle

Aubrey, TX 76227

&

124 South Fairfax

Alexandria, VA 22314

**Telephone:** 630-605-3022

**E-mail:** cadamshutt@rdrsol.com

**PROFESSIONAL SUMMARY:**

With experience in the public and private sectors, Dr. Adams Hutt provides advice and guidance on a wide range of food topics. Catherine has senior experience in health and wellness, business strategy, product development, regulatory compliance, food safety, quality systems management, supply chain, and software solutions for management of quality and product development processes.

Dr. Adams Hutt is a recognized expert and leader in the areas of nutrition, food safety, and regulatory matters and routinely supports clients as expert witness. She is also an accomplished leader for the creation and execution of strategic change designed for business results. She successfully works at the interface of disciplines for solutions; including nutrition, food safety, innovation, regulatory, quality, and food science. She excels at strategic analysis and problem solving and builds coalitions designed for results. Dr. Adams Hutt has senior

executive experience with the manufacturing and food service industries, trade associations and regulatory agencies in the Federal Government. Her business experience includes the creation, design and launch of innovative applications of global Quality and food safety management systems, supporting Quality and Product Development as cornerstones for successful business growth. She designed and executed nutrition strategy for a global business leading reformulation and product innovation designed to promote health. Catherine recommends and leads implementation of business strategies and new products designed for success using health and wellness as a business platform. She drove the creation and implementation of novel internet-based information management systems for product lifecycle management, aligning Research & Development, Nutrition, Marketing, Quality, Procurement and Operations. She also designed and drove implementation of supplier food safety and Quality management programs with proven results for enhanced effectiveness and efficiency, with integration of sustainable agriculture practices.

Dr. Adams Hutt has senior leadership experience in multiple Fortune 200 businesses and has been Chief Executive Officer for a bakery manufacturing business, leading a safety, production, and quality turnaround. She also has extensive experience with Federal and state regulatory policies delivering regulatory compliance and food safety. She has been a leader in nutrition, food safety, and quality programs with experience in organizing and managing teams in the manufacturing and food service industries. As Assistant Administrator of USDA's Food Safety and Inspection Service, she was the third highest ranking leader in the agency of over 7500 professionals.

Catherine is recognized by leadership teams and by her peers as a strategic visionary with strong business orientation and acumen, an innovative thinker, a decisive leader, and a demanding professional with extraordinary integrity and strong people skills. She is trained as a corporate media spokesperson and has exceptional communication and presentation skills.

**EDUCATION:**

PhD, Food Science, University of Illinois, Champaign-Urbana (1986)

MS, Food Science & Human Nutrition, Michigan State University, East Lansing (1981)

BS, Food Science, Pennsylvania State University, University Park (1979)

ISO 9000 Lead Assessor Program, Chipping Campden, UK (1992)

Carnegie Mellon University Senior Executive Management Program, Pittsburgh, PA (1990)

FDA Better Process Control School, University Park (1978)

Harvard Business School Agribusiness Seminar (2009)

**HONORS and CERTIFICATIONS:**

Graduation from Pennsylvania State University with Highest Distinction (First in Class) (1979)

US Federal Government, Senior Executive Service (inducted 1990)

Distinguished Alumnus, Pennsylvania State University College of Agriculture (1995)

Fellow, Pennsylvania State University (2008)

Fellow, Institute of Food Technologists (2009)

Member, Cosmos Club (inducted 2011)

Member, Phi Tau Sigma Honorary Society

Registered Dietitian

Certified Food Scientist

**WORK EXPERIENCE:**

***President and CEO, RdR Solutions Consulting, LLC***
***(June 2008 – Present)***

- Consulting organization with focus on for food safety, health and wellness, regulatory compliance, labeling, food safety policy, and quality systems management.
- Supports businesses with strategic guidance and problem-solving for food safety, regulatory compliance, and wellness platforms.
- Supports businesses to prevent and manage food regulatory and food safety crisis situations; provides expert witness in litigation cases.
- Directs new product development based on consumer trends and policy landscapes for health and wellness, and food safety.
- Supports regulatory compliance and brand development for functional foods, dietary supplements, and medical foods.
- Accomplished expert witness in food safety and food regulatory cases.

***Chief Regulatory and Science Officer, SloanTrends***

***(August 2011 – Present)***

- Interprets scientific literature and data in order to identify emerging consumer market opportunities in the food and beverage business.
- Creates sustainable business opportunities and customer-centric new product solutions for food and beverage, dietary supplement, pharmaceutical, foodservice, ingredient, and commodity board marketers.
- Provides trend interpretation, forecasts and actionable market recommendations; strategic counsel on media, regulatory, safety, quality system, and scientific issues.
- Develops cutting-edge product concepts with on-target marketing messages and regulatory claim positioning to protect and drive business.

***Chief Executive Officer, Landes Foods (designed to be short-term consultancy role)***
***(June 2015 – September 2015)***

- Led a $26M bakery manufacturing business, based in Dallas, Texas.
- Designed a turn-around for the privately-held company; building systems to drive improvements in safety, productivity, efficiencies, and quality performance.
- Drove Global Food Safety Initiative (GFSI) quality systems implementation.
- Changed the existing culture to one that is a safety, quality and recognition culture.
- Delivered programs that reduced employee turnover and accelerate quality improvements.
- Delivered programs that enhanced worker safety programs and processes.
- Drove new business opportunities that will substantially expand revenue, and profitability; rationalizing the supply and customer base in order to improve margin and profit.

***Senior Advisor, Leavitt Partners***
***(May 2010 – December 2013)***

- Provided consulting on food safety, quality systems, and health policy issues.

***McDonald's Corporation***
***Corporate Vice President, Worldwide Quality, Food Safety and Nutrition***
***Chief Quality Officer, WW Supply Chain***
***(January 2004 – June 2008)***

- Developed and implemented a nutrition strategy to support the global business.
- Worked closely with Worldwide Marketing, Worldwide Communications and WW Menu Management (Research and Development) to implement and promote improved nutrition guidelines.
- Served as a corporate media spokesperson on scientific issues including food safety, Quality and nutrition.
- Developed and implemented an appropriate approach for engagement with key influence agents, including health professionals and consumer activists.
- Led relationships with key food industry trade and professional associations.

- Developed food safety systems to optimally support appropriate food safety standards and practices worldwide for suppliers and restaurants.
- Led the development of a global supplier Quality management system and distributor Quality management system, including HACCP and statistical process control.
- Led the development of criteria for classifying suppliers according to risk and assigning appropriate risk-based audit standards.
- Led engagement for current and emerging food safety issues.
- Developed proactive strategies to protect the Brand.
- Sponsored the McDonald's Food Safety Advisory Council.
- Supported the Legal Team proactively and in litigation.
- Led the corporate worldwide quality team.
- Developed systems to optimally support quality standards and policies worldwide.
- Improved quality practices system-wide in order to deliver world-class products to consumers.
- Drove worldwide development and implementation of Quality management tools.
- Initiated and led the development and implementation of a state-of-the-art internet-based information system for managing products, suppliers and menu worldwide.
- Shared responsibility to support social responsibility policies for the global business, including animal welfare and environmental practices.
- Led the reorganization of our European Supply Chain team, including Quality, Food Safety and Procurement.

***Coors Brewing Company, Vice President Quality & Environmental Health & Safety (January 2003 – December 2003)***

- Led the development and implementation of enterprise-wide world-class Quality systems.
- Developed and delivered the strategy to build a Corporate Quality department with oversight responsibility for Quality and food safety for the global Coors' operations.
- Led the development of global web-based knowledge management systems.
- Led corporate compliance for environmental, health and worker safety programs.
- Led the development of rigorous corporate food security programs.
- Drove the delivery of a strong safety culture for all global sites.
- Led the Corporate team to define and deliver highly drinkable beers.
- Led the integration of social responsibility into the Quality agenda for the Company.

***Heinz North America & Frozen Foods, Quality Lead (September 1999 – December 2003)***

- Led the development and implementation of world-class Quality systems, including food security planning and execution.
- Managed food safety control programs, including crisis response planning and product disposition.
- Developed a business model for product and vendor approval supporting e-commerce.

***YUM! Brands (formerly Tricon Global Restaurants, Inc.) (included over 30,000 Pizza Hut, KFC & Taco Bell domestic & international restaurants), Head Food Safety and Restaurant Quality (September 1997 – August 1999)***

- Developed YUM! Brands as a leader in food safety for the global food industry.
- Developed and implemented YUM! Brands food safety crisis management program and led all food safety-related crisis responses.
- Led a Field food safety and restaurant quality team, supporting regulatory compliance and improved product quality.
- Developed and implemented food safety training and restaurant audit programs.
- Developed, installed and maintained a QA Hotline for YUM! Brands restaurants for domestic and international operations.
- Developed and maintained a centralized nutrition database and responded to customer inquiries/medical food sensitivities.

***Campbell Soup Company, Director Worldwide Quality Systems (June 1993 – September 1997)***

- Developed the concept and implementation strategy for a customized Quality and Food Safety management system based on ISO 9001 and HACCP for all Campbell businesses and plants worldwide (over 100 locations globally).
- Engineered an ISO 9001-based management system's novel application in R&D, Marketing, Sales and Engineering.
- Led a three-year strategic initiative for nutrition and health.
- Optimized the use of consumer complaints for improving product Quality.

***Grocery Manufacturers of America, Director Scientific Affairs (October 1991 – June 1993)***

- Represented the food manufacturing industry to Government agencies, including US Department of Agriculture, Food & Drug Administration, Centers for Disease Control and Environmental Protection Agency. Organized and sponsored the first ISO 9000 conference to be convened in the US for the food industry.
- Provided technical and administrative support for a lobbying committee addressing microbiological and chemical food safety.
- Served as an invited Expert Consultant to the EU Food-Linked Agribusiness Research Group on HACCP and predictive microbiology.

***US Department of Agriculture – Food Safety and Inspection Service, Assistant Administrator (April 1990 – October 1991) and Special Assistant to the Administrator (December 1987 – April 1990)***

- Initiated and led the development of HACCP as a regulatory tool for Federal and State regulatory programs.
- Served as a primary spokesperson for the Federal meat and poultry regulatory agency in national and international forums.

- Served as the scientific technical expert for the Agency and the Secretary of Agriculture on food safety and toxicology issues.
- Chaired national and international committees, including the Federal Advisory Committee on Microbiological Safety of Foods & the Codex Alimentarius Commission Committee on Food Hygiene (including the Codex HACCP Subcommittee which defined the current HACCP system and gained international consensus).
- Prepared and tabled the international proposal to the Agricultural Negotiations of the GATT Uruguay Round on Sanitary and Phytosanitary Regulations.
- Participated as an expert member of two World Health Organization consultative groups on (a) HACCP and (b) *Listeria monocytogenes*.
- Member of the US Department of Agriculture Cooperative Project for Technical Assistance to the Former Soviet Union.

***US Department of Agriculture – Extension Service, National Program Leader – Food Safety (May 1987 – December 1987)***

- Developed national food safety training program for county extension agents.

***International Life Sciences Institute – Nutrition Foundation, Director (January 1986 – May 1987)***

- Managed the International Vitamin A Consultative Group (IVACG) and International Nutritional Anemia Deficiency Consultative Group (INACG).
- Edited publications of IVACG and INACG.
- Facilitated annual conference for the two international collaborative bodies.
- Facilitated food microbiology and nutrition member committees.

**MAJOR PROFESSIONAL ACTIVITIES:**

1. Faculty Member, 4th Annual Global Food Law and Policy Summer Academy, Italy
2. Owner, Rialto Racing Stables – a Thoroughbred racing and breeding business
3. Owner, Rancho di Rialto – a working horse and cattle ranch in Aubrey, Texas
4. Former Member, Science Advisory Committee, Nature's Bounty
5. Member, Advisory Board, Greenonyx, LLC
6. Former Member, Advisory Board, Stonestop (a medical food)
7. Former Senior Advisor, PureTech Ventures
8. Former Member, CDC Food Safety Modernization Act (FSMA) Surveillance Working Group
9. Former Chair, Council III (Science & Technology), 2002 Conference for Food Protection (CFP); Delegate, CFP, Council III (2012 & 2014)
10. Former Member, American Heart Association Better Diet Business Committee
11. Former Chair, Institute of Food Technologists (IFT) Food Laws and Regulations Division
12. Former Board of Directors Member, IFT (elected position)
13. Former Board Member, Ready By 21 (Youth Development Non-profit Organization)
14. Candidate, IFT President (2011 & 2012)

15. Former Chair, IFT Food Executive Leadership Forum and Senior Food Official Engagement Committee
16. Grant Reviewer, US Department of Agriculture National Institute for Food and Agriculture (2011)
17. Charter Member, Armsby Honorary Society, Pennsylvania State University.
18. Member IFT (since 1978) and Former Chair Continuing Education Committee and Long-Range Planning Committee
19. Former Member, Pennsylvania State University Advisory Committee to the College of Agriculture; Former Member Volunteer Fund Raising Committee
20. Former Member: Pennsylvania 4-H Horse Program Endowment Committee
21. Former Advisory Board Member, AgriCapital Investments
22. Former Editorial Board Member and current reviewer, *International Journal of Food Control.*
23. Former Co-Chair, NFPA-SAFE Supplier Audit Council
24. Former US Delegate, FAO-WHO Codex Alimentarius Commission Food Hygiene Committee.
25. Former Co-Chair, HACCP Working Group, Codex Alimentarius Commission, Food Hygiene Committee
26. Former Member, US Delegation, FAO-WHO Codex Alimentarius Commission Committee on Import/Export Inspection & Certification.
27. Former Co-Chair, YouthPlaces Quality Program Committee, City of Pittsburgh

**Prior Legal Case Experience**

1. Shawn Love vs. Ruby Tuesday, Inc., Circuit Court for Baltimore City, Court File No. 24-C-14-002417 OT (Firm: KalbaughPfund & Messersmith; Jessica Relyea)

- Food safety event, provided expert report for the defense. Plaintiff withdrew the case. Expert for Defense.

2. Barbara J Frazier vs. Ruby Tuesday, Inc., Prince George's County District Court, MD, Case No. 0502000098952013 (Firm: KalbaughPfund & Messersmith; Jessica Relyea)

- Personal injury, safety; provided expert opinion for the defense. Plaintiff withdrew the case. Expert for Defense.

3. Eldredge D Williams vs. Westfam Restaurants et al., Civil action No. CV-2010-73; HC&D File No. 200-02038

- Food safety event; provided expert report and affidavit; the case settled before going to trial. Expert for Defense (Burger King restaurant).

4. Zentis Food Solutions North America LLC vs. Continental Food Sales and A&P Fruit Growers Ltd.; US District Court, Northern District of Indiana, South Bend Division. Case No. 3:11-CV-00425 – CAN (Firm: Kightlinger Grey; Erin Clancy)

- Food contamination event; reviewed physical plant and processing operations and provided expert opinion for the defense (blueberry processors); the case settled. Expert for Defense.

5. Clemmy's LLC vs. Nestle USA, Inc & Nestle USA, Inc vs. Clemmy's LLC; Superior Court of the State of California, County of Los Angeles, Central District, Case No. BC500811 (Firm: Girardi Keese; Alexandra Steele)

- Regulatory labeling compliance and standard of identity issue along with unfair trade allegations; provided expert summary of opinion and deposition regarding labeling rules, including naming and flavor identification; and standard of identity on behalf of Clemmy's. Deposed. Case settled without compensation to either side.

6. Insurance settlement for Garden Fresh Foods (Firm: Wade Clark Mulcahy)

- Industry best practice and due diligence investigation related to Class I recall.

7. Leslie Reilly vs Chipotle Mexican Grill, Inc, U.S. District Court Southern District of Florida, Case No. 1:15-cv-23425 COOKE/ TORRES (Firm: Harke, Clasby and Bushman, LLP; Sarah Harke)

- Class action for meat and poultry menu items sold as "non-GMO". Deposed. Case closed. Expert for Plaintiff.

8. Mr. Joshua Blancett vs Cargill Meat Solutions Corp, Civil Action No. 6:16-CV-00024-RP-JCM, Dallas, TX (Firm: Law Offices of David Sanchez, PC; James Trujillo)
- Foreign material and personal injury. Deposed. Expert for Plaintiff.

9. Ms. Caren Malone vs Arby's Restaurant Group, Inc., Richmond, VA (Firm: Alexander Law Group; Michael Krol)
- Food allergy. Expert for Plaintiff.

10. Far Away Springs vs. Niagra (Firm: Salmon Ricchezza Singer & Turchi, LLP; Debbie Doyle)
- Assessment of standard industry practice relevant to damages from food recall. Expert for Plaintiff.

11. Mr. Joseph Michaels vs. Valenti Southeast Management, LLC, Civil Case No. 01-CV-2016-903681.00 Circuit Court Jefferson County, Alabama (Firm: Heninger Garrison Davis LLC; W. Lee Gresham)

- Foodborne illness. Deposed. Expert for Plaintiff.

12. Graeter's Inc. vs. Tedesco LLC, Case No. A-17-00717 Court of Common Pleas Hamilton County, Ohio (Firm: Frost Brown Todd; Jeremiah Byrne)
- Industry Good Manufacturing Practices, food safety. Deposed. Expert at Arbitration. Expert for Defense.

13. Shawn F. Byrne and Amanda E. Byrne vs Taco Bell of America, LLC, Civil Case No. 2017-361-R, United States District Court for the Western District of Oklahoma (Firm: Phillips Murah PC; Amy White and Calvin Sharpe).
- Personal injury, alleged intentional adulteration. Expert for Defense.

14. Wanda Dexter vs. Baylor All Saints Medical Center, District Court of Tarrant County, Texas (Firm: Law Office of Darren Wolf, PC; Darren Wolf).
- Personal injury, burn. Expert for Plaintiff.

15. Dareen Ann Angerame and Thomas E. Angerame vs PIKR, Ltd, d/b/a Perry's Steakhouse and Grille, Cause No. D-1-GN-16-000180, District Court Travis County, Texas, 53rd Judicial District (Firm: Dorsett Johnson & Swift, LLP; Kevin Leahy).
- Personal injury, food allergy. Deposed. Trial. Expert for Plaintiff.

16. Michelle Lynch Francis vs Marriott International Inc., Civil Action File No. 2017CV290533, Superior Court for Fulton County, State of Georgia (Firm: Gray, Rust, St. Amand, Moffett and Brieske, LLP; Candis Jones)
- Norovirus event, Affidavit submitted. Expert for Defense.

17. Ralph D. Armes v. Olive Garden Store 4419, Case No.:CL18-576, Circuit Court of Tazewell County, State of Virginia (Firm: Kalbaugh Pfund & Messersmith PC; Jessica Relyea)
- Food poisoning event, Deposed. Expert for the Defense.

18. Jonathan B. Grooms v. Duncan Hines. Insurance Claim A003361080. (Firm: Marc Walwyn Attorney at Law; Marc Walwyn)
- Personal injury. Expert for the Plaintiff.

19. Cargill v. CR England. Insurance claim. (Firm: Baker Botts, John Anaipakos)
- Loss claim. Expert for the Defense.

20. Julia Escobedo v. Popeye's Louisiana Kitchen, Inc. D/B/A Popeye's Chicken. Cause No. C-2782-16-B, District Court of Hidalgo County, Texas (Firm: Griffith Law Group; Burt Harrison)
- Food poisoning. Expert for the Defense.

21. Melissa White v. Steak n Shake, Inc. Cause No. 4:18-CV-0072 RWS, in the United States District Court, Eastern District of Missouri, Eastern Division. (Firm: Henderson Law Firm; Samuel Henderson)

- Foreign material. Deposed. Expert for the Plaintiff.

22. F.E.I. Company vs. United States of America. Civil Action No. 1:16-02237, in the United States District Court for the Middle District of Pennsylvania. (Firm: Leger Ketchum & Cohoon, PLLC, Patrick Cohoon)
- Adulterated product definition. Deposed. Testified at Trial. Expert for the Plaintiff.

23. Brandstorm vs. Global Sterilization and Fumigation. (Firm: Daley & Heft, LLP, Heather Daiza)
- Product damage. Expert for the Plaintiff.

24. Kensu et al vs Michigan Department of Corrections. U.S. District Court Eastern District of Michigan, Southern Division, Case 2:18-cv-10175 (Firm:
Excolo Law and The Law Office of Keith Altman, Keith Altman)
- Nutritional adequacy of prison diet. Deposed. Expert for the Plaintiff.

25. Mingxi Zou vs Montgomery County Government. (Firm: Malloy Law Offices, LLC, Seann Malloy)
- Scald burn. Expert for the Plaintiff.

26. People of the State of California v. Nutraceutical Corporation. Superior Court of the State of California for the County of Alameda. Case No. RG18907841 (Firm: Buchalter, Dennis Raglin)
- Technical support for Prop 65 issue. Expert for the Defense.

27. Zest labs, Inc F/K/A Intelleflex Corporation and EcoArk Holdings, Inc v. Walmart, Inc F/K/A Wal-Mart Stores, Inc. Case No.4:18CV00500 JM in the United States District Court Eastern District of Arkansas, Central Division (Firm: Skadden, Arps, Slate, Meagher and Flom, LLP, P. Anthony Sammi; and Winston and Strawn, LLP, John R. Keville)
- Intellectual property dispute regarding supply chain and quality software, agriculture, and quality systems best practices. Deposed. Testified at Trial. Expert for the Defense.

28. Steak N Shake Inc. v. Melissa White, U.S. District Court Eastern District of Missouri Eastern Division. Case No. 4:18-cv-00072-RWS (Firm: Henderson Law Firm, Samuel Henderson)
- Food adulteration and foodservice industry best practices. Deposed. Expert for the Plaintiff. Testified at Trial.

29. Sentinel Insurance Company, Ltd., v. VLM Foods, Inc, et al., U.S. District Court for the Eastern District of Virginia. Case No. 1:19-cv-01395 LMB/TCB (Firm: Kramon & Graham PA, Ezra Gollogly)
- Hepatitis A outbreak at a foodservice establishment, industry best practices. Expert for the Plaintiff.

30. Kurt Williams, as next friend and guardian of Q.W., a minor v. Braum's Incorporated, U.S. District Court of Cleveland County, State of Oklahoma. Case No: CJ-2018-921 (Firm: Durbin Larimore Bialick, Thomas Kendrick)

- Personal injury, burn, industry best practices. Expert for the Defense.

31. Shemal Scott and Marlon Scott v. Smoothie King Franchises, Inc. State Court of Muscogee County, State of Georgia. (Firm: Gary, Rust, St. Amand, Moffett & Brieske, LLP, Jared Jacobs)
- Ingredient safety. Expert for the Defense.

32. United 1 v Fas-Pac. (Firm: Macdonald and Devin, Steve Baggett)
- Product contamination. Expert for the Defense.

33. Jennifer Manders & Trilogy Health Insurance, Inc vs Margarita's of Wisconsin, Inc & Erie Insurance Company. Circuit Court of Brown County, State of Wisconsin. Case No. 19 CV 1421 (Firm: Simpson & Deardorff SC, Heidi Melzer).
- Foodborne disease outbreak. Expert for the Defense.

34. Mary Sue Butler vs. Ace Eateries D/B/A Denny's. Cause #C-2527-18-B, District Court 93rd Judicial District, Hildago County, Texas. (Firm: Griffith Law Group, Burt Harrison).
- Food contaminant. Expert for the Defense.

35. Ginsberg *et al* vs. Vitamins Because LLC *et al.* United States District Court Southern District of Florida. Case No. 1:19-CV-22702-KMW. (Firm: Kantrowitz, Goldhammer, and Graifman, PC, Jay Brody).
- Labeling matter regarding dietary ingredient SAMe. Fact witness for the Defense. Deposed.

36. KIND LLC "Healthy and All Natural" Litigation. United States District Court for the Southern District of New York. Case No. 1:15-MD-02634 WRP. (Firm: Mayer Brown, LLP, Jillian Joseph). Expert for the Defense. Deposed.

37. Michael Testone, Collin Shanks, and Lamartine Pierre on behalf of themselves, all others similarly situated, and the general public vs. Barlean's Organic Oils, LLC. United States District Court for the Southern District of California. Case No. 19-CV-0169-JLS-BGS. (Firm: Gordon Rees Scully Mansukhani, LLP, Gabriel Hedrick).
- Claims validation for healthfulness. Exert for the Defense. Deposed.

38. Eleazar Lucio Castillo vs. A3H Foods, LP, D/B/A Jack in the Box, A3H Foods General Partner, LLC. United States District Court for the District Court of Harris County, Texas, 269th Judicial District. Cause No. 2020-24371. (Firm: The Corona Law Firm, Jesse Corona).
- Adulteration with a foreign object. Expert for the Defense.

39. Roxanne Stone and Jacqueline Hill vs. Lystn, LLC and Lystn, LLC vs Jacqueline Hill, Roxanne Stone, and Initial LLC. Court of Common Pleas in Berks County, Pennsylvania. Civil Action Law & Equity No: 21-11790. (Firm: Cornerstone Law, Joel Ready).
- Intellectual property, trade secrets. Expert for the Plaintiff and Defense. Deposed. Trial.

40. Bradley Burford, Individually and As Administrator of the Estate of Karen Skorvanek, Deceased vs. Autumn Aegis, Inc. et al. Court of Common Pleas Lorain County, Ohio. Case No. CV203146. (Firm: Marshall Dennehey, Leslie Jenny).
- Personal injury, choking, nursing home. Expert for the Defense.

41. Susie Zapata and Monica Garcia vs. Leon Martinez, Roberto Lucero-Ortega, Arthur Sanchez, Berleen Estevan And Summit Food Service, LLC. United States District Court for the District of New Mexico. Case No: 1:21-cv-00083-MV-JFR. (Firm: Civerolo, Gralow & Hill, PA, Lisa Pullen).
- Industry best practice, sanitation. Expert for the Defense.

42. Jose Pablo Arzola vs. MTC, Inc. D/B/A Pico di Gallo Restaurant. United States District Court for the District of Bexar County, Texas, 288th Judicial District. Cause No. 2020-CI07721. (Firm: Milton I. Fagan PLLC, Milton Fagin).
- Foodborne illness. Expert for the Plaintiff.

43. Rita Masters and Robert Masters vs. Cracker Barrel Old Country Store, Inc, And Rose Acre Farms, Inc. United States District Court for the Eastern District of North Carolina, Western Division. Case No. 5:21-CV246-D. (Firm: Young, Moore and Henderson, PA, Christopher Page).
- Foodborne illness, product recall effectiveness. Expert for the Defense.

44. Crayex vs. Brakebush (Firm: Fee, Smith, Sharp & Vitullo, LLP, Howard Klatsky).
- Food adulteration, sanitation. Expert for the Defense.

45. Sandra Friesner, Deceased vs. Ridge Crest Nursing Center. (Firm: Bley & Evans, Mark Evans).
- Personal injury, choking, nursing home. Expert for the Plaintiff.

46. Simmons vs. Abbott Laboratories. (Firm: Branstetter, Stranch & Jennings, PLLC, Ben Gastel).
- Risk of NEC from infant formula. Class Action. Expert for the Plaintiff.

47. Amannett Jennings vs. Roman Catholic Diocese of Amarillo and St. Joseph Catholic Church. District Court of Potter County, Texas Cause No. 111052-2-CV. (Firm: Thomas Riney, Underwood Law).
- Foodborne illness. Class Action. Expert for the Defense.

48. Paw, Administrator of the Estate of Bosco Htoo vs. Bunzl. Court of Common Pleas, Philadelphia County. SEA Matter No. 04.128064. (Firm: Ricci, Tyrrell, Johnson & Gray, Patrick McStravich).
- Standard of care for personal protection equipment. Expert for the Defense.

49. Tony Langione vs. Popeyes Chicken & Biscuits. County Court at Law No. 4, Dallas, Texas. Cause No. CC-20-02593-D. (Firm: Robert C. Slim Law Firm, PLLC, Robert Slim).
- Foodborne illness. Expert for the Plaintiff. Trial.

50. Bianca Paige vs. Washington State Department of Corrections. In the Superior Court of the State of Washington and for the County of Pierce. Case No. 21-2-07660-4. (Firm: Herrmann Law Group, Anthony Marsh).
- Norovirus foodborne illness. Expert for the Plaintiff.

51. Leslie Ainsworth et al vs. Walmart, Inc. United States District Court, Eastern District of Arkansas. Case No.:3:21-cv-00082-DPM. (Firm: Scott + Scott, Erin Green Comite).
- Heavy metals in baby foods. Class Action. Expert for the Plaintiff.

52. Sherie Jenkins et al vs. ProSource Produce, LLC. United States District Court for the District of Idaho. Case No. 1:22-cv-00044. (Firm: ScottHulse PC, Jimmy Feuille).
- Salmonella foodborne illness. Class Action. Expert for the Defense.

53. Orion Gallagher et al vs AffinityLifestyles.com, Inc D/B/A Real Water. District Court, Clark County, Nevada. Case No.: A-21-8344485-B. (Firm: Kemp Jones, Will Kemp).
- Adulteration of alkaline water for retail. Class Action. Expert for the Plaintiff. Deposed.

54. Crider, Inc., vs Silgan Containers LLC and Silgan Containers Manufacturing Corporation. United States District Court for the Northern District of Texas. Civil Action No. 3:21-cv-01047-M. (Firm: Greenberg Traurig, Joseph Griffith).
- Pitting corrosion and black sulfide staining in canned protein products. Expert for the Defense. Deposed.

55. Cory Fulmore vs Landry's Inc., d/b/a The Original Joe's Crab Shack Joe's Crab Shack, LLC and XYZ Insurance Company. 19th Judicial District Court, East Baton Rouge Parish, State of Louisiana. Docket No. C-705107, Division 26. (Firm: Kean Miller, LLP, Ross Roubion).
- Food poisoning, shellfish. Expert for the Defense.

56. Innovative Solutions International, Inc. vs. Pilgrim's Pride Corporation Houlihan Trading Company, Inc. United States District Court for the Western District of Washington at Seattle. Case No 2:22-cv-00296-JCC. (Firm: Preg, O'Donnell & Gillet, Jamie Cheatham).
- Excessive bone in product, standard industry practices. Expert for the Defense.

**Publications:**

Adams CE and Morgan KJ (1981) Periodicity of eating: implications for human food consumption. *Nutr Res* 1(5): 525-550.

Adams CE and Erdman JW (1988) Effects of home food preparation practices on nutrient content of foods. In: Nutritional Evaluation of Food, Eds. Karmas E and Harris RS. AVI: New York, pp. 557-606.

Adams CE et al (1992) HACCP systems in regulatory inspection programs: case studies of USDA, USDC, and DOD. In: HACCP: Principles and Applications. Ed: Pierson MD. Springer: New York, pp.115-125.

Adams CE (1994) ISO 9000 and HACCP systems. *Food and Drug Law J* 49:603.

Adams CE (1994) HACCP as applied in the USA. *Food Control* 5(3): 187-189.

Adams CE (2002) Hazard analysis and critical control point – "original spin". *Food Control* 13:355-358.

Adams CE (2007) Reframing the obesity debate: role of McDonald's may surprise you. *J Law Medicine and Ethics* 35(1):154-157.

Adams Hutt CE (2010) Does being small mean less food safety risk? The e-Perspective, *Food Tech*, posted Dec 1.

Adams Hutt CE and Gonzalez M (2014) Food labeling. In: Encyclopedia of Agriculture and Food Systems 2nd ed. Ed, Van Alfen N Academic Press: London, pp.167-185.

*Nutraceuticals World*: Authors: Sloan E and Adams Hutt CE

Getting Ahead of the Curve: Prebiotics - March 2013

Getting Ahead of the Curve: Eye health and vision – May 2013

Getting Ahead of the Curve: Hispanics and health – July 2013

Getting Ahead of the Curve: Choline – Oct 2013

Getting Ahead of the Curve: Sleep – Dec 2013

Getting Ahead of the Curve: Turmeric and curcumin – March 2014

Getting Ahead of the Curve: Protein generation II – May 2014

Getting Ahead of the Curve: Amino acids – July 2014

Getting Ahead of the Curve: Organic – October 2014

Getting Ahead of the Curve: Magnesium and potassium – December 2014

Getting Ahead of the Curve: Kids health – March 2015

Getting Ahead of the Curve: Mobility – May 2015

Getting Ahead of the Curve: It's a natural – July 2015

Getting Ahead of the Curve: Fortification – Oct 2015

Getting Ahead of the Curve: Gluten-free 2015+ - Dec 2015

Getting Ahead of the Curve: Antioxidants – March 2016

Getting Ahead of the Curve: Women's health – May 2016

Getting Ahead of the Curve: Herbs and botanicals – July/Aug 2016

Getting Ahead of the Curve: Digestive health - Oct 2016

Getting Ahead of the Curve: Weight control – Dec 2016

Getting Ahead of the Curve: Global nutritional hot spots – March 2017

Getting Ahead of the Curve: Sleep – May 2017

Getting Ahead of the Curve: Sustainability Gen 2 – Dec 2017

Getting Ahead of the Curve: Conditional redirections – May 2018

Getting Ahead of the Curve: Naturally clean – July/Aug 2018

Getting Ahead of the Curve: Consumers seeking specialty nutritionals – Dec 2018

Getting Ahead of the Curve: Digestive health Gen 2 – April 2019

Getting Ahead of the Curve: Energy Gen 2 – July/Aug 2019

Getting Ahead of the Curve: Perspectives on Protein – Plant-based and beyond – October 2019

Getting Ahead of the Curve: Cognitive fitness – Dec 2019

Getting Ahead of the Curve: Natural sleep aids – Gen 2 – Mar/April 2020

Getting Ahead of the Curve: Immunity in the new normal – May/June 2020

Getting Ahead of the Curve: Food as medicine – July/August 2020

Getting Ahead of the Curve: COVID refocuses attention on heart health –

Sept/Oct 2020

Getting Ahead of the Curve: The Exercise as Medicine Movement – Dec

2020

Getting Ahead of the Curve: Pet Foods, Treats, and Supplements – May 2021

Getting Ahead of the Curve: Sustaining Plant-based Momentum, A Cautionary Tale - June 2021

Getting Ahead of the Curve: Minding Mental Health – Oct 2021

IFT “Food Disruptors” Podcast Episode19: Trends and Consumer Behavior in the Times of COVID-19: Food Retail. IFT.org, May 2020

IFT “Food Disruptors” Podcast Episode 20: Trends and Consumer Behavior in the Times of COVID-19: Food Service. IFT.org, May 2020

IFT “Food Disruptors” Podcast Episode23: Food Safety Experts on Recalls, Coronavirus, and Traceability. IFT.org, May 2020

Exhibit 28

## Contact

www.linkedin.com/in/erichzicher (LinkedIn)

## Top Skills

Quality Assurance
HACCP
Food Safety

## Certifications

Preventive Controls Qualified Individual
HACCP
A3 Problem Solving for Continuous Improvement
Food Processing Sanitation/Hygiene
Food Safety and Sanitation for Food Plants

# Erich Zicher

Quality Assurance; Food Manufacturing; Lean Management; FDA; USDA; HACCP; PCQI
Schaumburg, Illinois, United States

## Summary

Experienced quality and regulatory professional that leads with strong strategic vision and continuous improvement mindset. Team collaborator that excels at process analysis, innovation and mentoring of personnel.

## Experience

### creative werks, llc
Director of Food Safety
November 2020 - Present (2 years 10 months)
Elk Grove Village, Illinois, United States

### Hearthside Food Solutions / Greencore
Quality Assurance Manager
May 2017 - January 2020 (2 years 9 months)
Carol Stream, IL

Refrigerated food packaging facility producing ready to eat, perishable convenience meals under joint regulation of USDA and FDA. Organizational flagship location that manufactured over a half billion units and exceeded $329 million dollars in revenue in 2018.

### Greencore
Project Manager
October 2017 - April 2018 (7 months)
United States

Temporary Project Role -
Managed corporate facility sanitation gap assessment and standardization process across ten facilities in seven states. Project objectives included gap assessment and auditing, best practice sharing, and personnel/staffing level evaluation.

### PEACOCK FOODS / GREENCORE
5 years 4 months

### Quality Assurance Manager
September 2013 - May 2017 (3 years 9 months)
Bolingbrook, IL

FDA regulated dry and shelf stable facility that has produced over a half billion units annually between 2013 and 2017 and averages over $33 million dollars in annual revenue.

### Quality Assurance Supervisor
February 2012 - September 2013 (1 year 8 months)
Bolingbrook, IL

### Alpha Baking
2 years 9 months

### Director of Sanitation
November 2009 - February 2012 (2 years 4 months)

FDA regulated commercial bakery producing pan bread, rolls and buns for nationwide and international distribution, both in fresh and frozen segments. Facility made product for private label in addition to co-manufacturing and sourced manufacturing for retail and foodservice.

### Director of Quality Assurance
June 2009 - November 2009 (6 months)

## Education

### Arizona State University
Bachelor of Science - BS, Biochemistry

### Harper College
Associate of Arts - AA, Music

### AIB International

### Eastman School of Music
BA (3 years complete), Trombone Performance · (1999 - 2002)

### John Hersey High School

Exhibit 29

## Erich Zicher

Quality Assurance; Food Manufacturing; Lean Management; FDA; USDA; HACCP; PCQI

Schaumburg, Illinois, United States

729 followers · 500+ connections

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creative werks, llc

Arizona State University

## Activity


**this is a no-brainer...you don't achieve KPIs unless you achieve the following other "KPI"s... then it falls into place naturally.**

Liked by Erich Zicher


**So happy to be able to lend some insight into innovation for this article! Special thanks to @PackagingDigest for publishing my piece on innovation.…**
Liked by Erich Zicher


**Degrees have *officially* conferred at ASU (a month later) and I'm officially an alumni now! So beyond thrilled to have this behind me and my future…**
Liked by Erich Zicher

Join now to see all activity

## Experience

**Director of Food Safety**
creative werks, llc
Nov 2020 - Present · 2 years 3 months
Elk Grove Village, Illinois, United States

**Quality Assurance Manager**
Hearthside Food Solutions / Greencore
May 2017 - Jan 2020 · 2 years 9 months
Carol Stream, IL

Oct 2017 - Apr 2018 · 7 months

United States

**PEACOCK FOODS / GREENCORE**

5 years 4 months

**Quality Assurance Manager**

Sep 2013 - May 2017 · 3 years 9 months

Bolingbrook, IL

**Quality Assurance Supervisor**

Feb 2012 - Sep 2013 · 1 year 8 months

Bolingbrook, IL

**Alpha Baking**

2 years 9 months

**Director of Sanitation**

Nov 2009 - Feb 2012 · 2 years 4 months

Greater Chicago Area

**Director of Quality Assurance**

Jun 2009 - Nov 2009 · 6 months

## Education

**Arizona State University**

Bachelor of Science - BS

**Harper College**

Associate of Arts - AA

**AIB International**

-

**Eastman School of Music**

BA (3 years complete)

1999 - 2002

**John Hersey High School**

-

**A3 Problem Solving for Continuous Improvement**
LinkedIn
Issued Mar 2021
See credential

**Preventive Controls Qualified Individual**
Food Safety Preventive Controls Alliance (FSPCA)
Issued Sep 2016
Credential ID 75d90fbe

**Implementing SQF Systems (Post Farm Gate)**
SQF Institute
Issued Feb 2014
Credential ID A0011893

**Food Safety and Sanitation for Food Plants**
AIB International, Inc
Issued Jan 2011

**Food Processing Sanitation/Hygiene**
Amercan Institute of Baking
Issued Sep 2010

**HACCP**
International HACCP Alliance
Issued Sep 2010
Credential ID (renewed Septempber 2015)

**10-hour Occupational Safety and Health Training**
OSHA
Issued Jul 2010

## Recommendations received

**Matt Burke**
“Erich is the type of manager that you learn from daily. He is very hands on with his staff and continuously pushes them to reach their potential. His attention to detail and drive to learn makes him a major asset to any company. The best part about working with Erich is his positive attitude and his willingness to stop anything to help fellow colleagues. I valued my time spent with Erich as my manager.”

and standardizing work. He consistently demonstrated a solid work ethic and sense of urgency. We collaborated on an ERP system roll out across multiple sites in my division and he was instrumental in the training of staff for implementation. Erich is dedicated, self-motivated, methodical and reliable. He is not only a forward thinking Department Manager but also inspirational in his enthusiasm."

3 people have recommended Erich

Join now to view

## More activity by Erich

**Proud to be a part of this incredible team!** ⛳
Liked by Erich Zicher

**7 years as a FA with United, 5 years of flight training, instructing and time building, many struggles and tears, I finally able to make the…**
Liked by Erich Zicher

**Come see me at Booth# 1665! I'll be here all afternoon at IFT First! #iftfirst #IFT #chicago**
Liked by Erich Zicher

## View Erich's full profile

Contact Erich directly

Join to view full profile

d

g & Maintenance at creative werks, llc

nt Services and Information Technology at creative werks, llc

a
ty Manager

ufacturing and Engineering at Creative Werks LLC

ety & Quality Assurance Professional

A
g Manager at creative werks, llc

Supervisor | Warehousing | Logistics | Program Management | Quality Assurance / CAPA /
ents | Change Agent

idual with Quality Control and operations experience looking for an opportunity to add
rough learning and demonstrating exceptional work ethic and team work.

anager at creative werks, llc

vate Label and Brand Project Development and Management; Operations Continuous

ce Hub

## n these courses

**'our Android App for Kotlin Developers**

**ef**

**Structures: Sets and Frozen Sets**

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on other websites

Food Manufacturing; Lean Management; FDA; USDA; HACCP; PCQI

r at creative werks, llc

y

Linked in

Exhibit 30

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

MARY MADISON,

Plaintiff,

v.

Case No. 23CV16476

Honorable Judge Manish S. Shah

CREATIVE WERKS, LLC,

and Steve Schroeder, individually,

Defendants.

**DECLARATION OF JORDAN T. HOFFMAN**

I, Jordan T. Hoffman, declare as follows:

1. I am an Attorney licensed to practice law in the state of Illinois and was retained by Mary Madison in connection with a Department of Labor matter, claim no. 301015087. I have personal knowledge of the facts stated herein and, if called as a witness, could and would competently testify thereto.

2. On December 20, 2022, I attended a meeting with Mary Madison and outside legal counsel for Creative Werks, LLC, specifically Attorney Ross of the law firm Ford Harrison. The meeting lasted over seven hours and was described by Defendants as an "independent fact-finding" interview.

3. During that meeting, Attorney Ross questioned Ms. Madison for more than six hours, primarily concerning her past employment history, including topics that Defendants have subsequently identified as after-acquired evidence. Only approximately one hour of the

discussion focused on the Risk Analysis materials Ms. Madison had submitted to Mr. Schroeder on October 21, 2022.

4. During the meeting, both Ms. Madison and I communicated that the process conducted by Defendants' outside counsel appeared to be a contrived pretext, a subsequent remedial measure, and a smokescreen rather than a legitimate or neutral investigation.

5. Several weeks later, during the week of January 11, 2023, I was contacted by Ford Harrison and subsequently spoke with Attorney Craig Thorstenson on January 17, 2023. He stated that he was calling on behalf of Creative Werks, LLC, regarding the outcome of the alleged investigation.

6. During that call, Mr. Thorstenson extended a severance offer of $50,000 and stated that Ms. Madison would not be permitted to return to work at Creative Werks because "Eric Zicher could not work with her." He also stated that Ms. Madison's allegations and complaints were "unfounded."

7. I communicated the content of that discussion to Ms. Madison. In response, she submitted additional documentation to Defendants outlining her legal claims, including disparate treatment, retaliation, and other causes of action. She also requested the results of the investigation and a copy of her complete personnel file.

8. Mr. Thorstenson, on behalf of the Defendants, asserted that the results of the investigation were privileged and refused to disclose them. I objected to that claim. (See **Exhibit 1**.)

9. Mr. Thorstenson also refused to provide Ms. Madison with her personnel file, stating it had been previously produced in November 2022 and that the only additions were materials submitted by Ms. Madison herself. It was my further understanding that the suspension letter of October 26, 2022, was the only adverse thing in Ms. Madison's personnel file (See **Exhibit 2**.)

10. In the weeks that followed, Mr. Thorstenson communicated with me several additional times regarding the severance proposal. He inquired about whether Ms. Madison would make a counteroffer and acknowledged that the Defendants were aware of the legal claims Ms. Madison had raised. These discussions are reflected in a number of written correspondences exchanged between myself and Defendants' counsel, Mr. Thorstenson, from Ford Harrison Law Firm. Settlement communications ceased around April 2023.

11. I was not informed by Defendants, Mr. Thorstenson, or any other representative that Ms. Madison had been terminated. I did not learn of this alleged termination until July 2023, when Defendants submitted a response to the Department of Labor in connection with Ms. Madison's whistleblower complaint. (See **Exhibit 3**.)

12. It was in that context that I first became aware that Defendants were asserting Ms. Madison had been terminated for alleged incompetence. I have never been provided with a termination date, supporting documentation, or any evidence to substantiate those claims. Nor did Mr. Thorstenson ever notify me during our previous communications that Ms. Madison had been terminated.

13. I have never authorized or granted an extension of time for Defendants to file an answer in the matter pending before the United States District Court for the Northern District of Illinois. I have also never represented to Defendants or the Court that I am counsel of record in that matter, as I am not a member of the Federal Trial Bar.

14. In the days leading up to the hearing on Ms. Madison's motion for default judgment, Defendants' counsel emailed me, referencing the motion and insisting that I either assist in withdrawing it or align with their pleadings. They further threatened that, if I declined, they would submit statements I perceived as coercive—intended to gain an unfair litigation advantage through the use of such threats or assertions.

15. I declined to assist them in that regard. Defendants' counsel followed through on their threat. At Ms. Madison's request, I executed and filed an affidavit with the Court outlining the substance of this exchange and the improper conduct of Defendants' counsel.

16. I declare under penalty of perjury under the laws of the United States of America that the foregoing statements and documents are true and correct.

Executed on this 22 day of June, 2022

**/S/**

**Jordan T. Hoffman, Esquire**

**2711 East New York St., Suite 205**
**Aurora, IL 60502**
**888.958.4529 Phone and Facsimile**

Exhibit 30-1

Gmail **Jordan Hoffman <jthoffmanlaw@gmail.com>**

# Mary Madison: Statement; Risk Analysis and Personnel File Requests

**Craig R. Thorstenson** <CThorstenson@fordharrison.com> Fri, Jan 20, 2023 at 10:53 AM
To: Jordan Hoffman <jthoffmanlaw@gmail.com>

Hi Jordan

I've asked Creative Werks to pull together Madison's personnel file and will provide them to you. She specifically asks for the investigation findings in her request. We will not be providing any investigation report or findings because they are subject to the attorney client privilege.

[Quoted text hidden]

*ATTORNEY WORK PRODUCT - PRIVILEGED & CONFIDENTIAL*

Gmail **Jordan Hoffman <jthoffmanlaw@gmail.com>**

# Mary Madison: Statement; Risk Analysis and Personnel File Requests

**Jordan Hoffman** <jthoffmanlaw@gmail.com> Fri, Jan 20, 2023 at 11:59 AM
To: "Craig R. Thorstenson" <CThorstenson@fordharrison.com>

Good morning, Craig. Thank you for your response. Surely, the attorney-client privilege doesn't extend to the in-house communications between the decision makers that are in Ms. Madison's file relative to Creative Werk's preliminary investigation that lead to her suspension.

Jordan

The Law Office of
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888.958.4529 Phone and Facsimile
jthoffmanlaw@gmail.com

***"Balancing the Scales of Justice"***

www.attyjthoffman.com



[Quoted text hidden]

Exhibit 30-2

Gmail

**Jordan Hoffman <jthoffmanlaw@gmail.com>**

# Mary Madison and Creative Werks

**Craig R. Thorstenson** <CThorstenson@fordharrison.com> Tue, Feb 14, 2023 at 8:59 AM
To: Jordan Hoffman <jthoffmanlaw@gmail.com>

Hi Jordan,

Creative Werks mailed the W-2 to Ms. Madison about a month ago and it has not been returned. I've attached another copy. The attached is password protected and I will provide the password in a separate email.

I've also attached the separation agreement with Creative Werk's offer of separation pay and the terms.

As to Ms. Madison's January 19, 2023 request for her personnel records, as I previously indicated, Creative Werks provided Ms. Madison with her personnel records on 11/8/2022 in response to a request she made on 11/7/2022. The only additional documents are all documents Ms. Madison provided to Creative Werks and are titled the following: Regulatory Business Problem dated October 20, 2022; Legal Analysis of Regulatory Business Problem dated November 15, 2022; Madison Opening Statement 12.20.2022; and Madison's 1/23/2023 letter to Creative Werks re Response to Outcomes and Findings of investigation relative to the October 20, 2022 Risk Analysis and October 21, 2022 conversation with Mr. Steve Schroeder. You and Ms. Madison already have each of these documents.

[Quoted text hidden]

**2 attachments**

**M. Madison W-2 2022.PDF**
8K

**Creative Werks M. Madison Separation Agreement 2.13.2023.DOCX**
46K

July 10, 2023

VIA EMAIL (Bailey.Amy@dol.gov)

Amy Bailey
U.S. Department of Labor - OSHA
230 S. Dearborn St., Suite 3244
Chicago, IL 60604

Re: Creative Werks-Madison. Claim No. 301015087

The law firm of Dickinson Wright PLLC hereby sets forth this Position Statement on behalf of Creative Werks LLC ("Creative Werks") in response to the Complaint filed by Complainant, Mary Madison ("Madison" or "Complainant"), in the above referenced matter.

Creative Werks did *not* terminate Madison in retaliation for whistleblowing and/or engaging or identifying non-compliance with requirements of the Food Modernization and Safety Act ("FSMA") or other applicable food safety and regulation issues. Indeed, Creative Werks (a food contract packager or co-packer) specifically hired Madison in September 2022 as a Quality Regulatory Manager for *the very purpose of reviewing, revising, reporting on and helping to maintain Creative Werks' FDA regulatory compliance*. Rather, Creative Werks terminated Madison because she overstepped her supervisor and presented a 78-page document, entitled a "Regulatory Business Problem" (the "Report") directly to Creative Werks' President. Creative Werks attaches a copy of the Report as Exhibit A. The Report consisted of unsupported conclusions and manifestly unprofessional statements. Furthermore, it contained intentional distortions of objective data along with unsupported, alarmist and irrational findings, which reflected Madison's failure to rely upon the documentary evidence at her disposal. It also contained gross misstatements of the law, intentional omissions of information showing an intent to distort facts to reach unsupportable conclusions, misrepresentations of Creative Werks' existing and

robust food safety processes, and false allegations *objectively disputable* and known to be false by Complainant. In all, the Report reflected materially poor "work product" for someone specifically hired to assist with Creative Werks' food safety and regulatory compliance, and it showed a lack of the skills and knowledge needed for her job.

Likewise, many allegations made in her Department of Labor Complaint (the "Complaint") reflect the same deficiencies in the Report that led to her termination. The Complaint also continues Madison's use of demonstrably false and misleading statements and allegations, which are addressed in detail herein.

Detailed declarations from Madison's supervisor, Mr. Erich Zicher – Creative Werks' Director of Food Safety ("Zicher"), and Dr. Kathy Knutson ("Knutson"), a food safety regulatory expert, who was given unfettered access to the Company's records, are included along with this Position Statement and support Creative Werks' arguments and positions herein.

This Position Statement establishes that Creative Werks did not fire Madison because of any whistleblower activities, nor was she otherwise retaliated against for bringing legitimate packing/regulatory/safety issues to Creative Werks' attention. Rather, Creative Werks terminated her for her demonstrable lack of competence, lack of proper priorities, and apparent inclination to distort objective facts toward the ends of asserting her unsupported, alarmist, and improper conclusions – all of which were wholly inconsistent with her job duties.

By way of context, Madison drafted her seventy-eight (78) page Report less than four (4) weeks after being hired, which she somehow completed in addition to her assigned business duties. She did not provide this Report to her direct supervisor, Zicher, for vetting, review, or discussion. Rather, she bypassed all typical procedure and presented her Report to Creative Werks' owner and president, ignoring well-set corporate structure and its inherent checks and balances.

**The Expert Report**

Knutson's expert report (the "Expert Report") contains a detailed description of her qualifications therein. (See Exhibit B.) In short, she is an experienced food safety manufacturing compliance consultant, a Food Safety Preventive Controls Alliance ("FSPCA") Lead Instructor for the training of Preventive Control Qualified Individuals (PCQIs), with over 50 training courses in the 20-h standardized curriculum, wherein the FDA requires a PCQI as a member of the food safety team at every food/food packing facility. As a consultant, she works with Quality Managers in the food industry to write their hazard analysis, Food Safety Plans, Standard Operating Procedures (SOPs), document templates, and recall plans. She also has a Ph.D. in Food Science, and her work experience includes roles in education and laboratory operations for food testing and analysis.

The below excerpts from the Expert Report are only a sampling of the subjectively and objectively outrageous, unsupported, exaggerated, and factually distorted work product existing in the Report, in all representing a lack of proper executive thinking and logical analysis.

In material part, the Report sets forth the following conclusions and recommendations, which as described below are entirely unfounded and based on intentionally misleading information:

a. Creative Werks LLC's non-compliance with the relevant statutes, standards and regulations under FSMA is an *inherent systematic and systemic issue throughout the organization that creates irreparable harms for all stakeholders*. (Emphasis added.)

*b.* More specifically for Creative Werks LLC, this non-compliance *creates legal liability and culpability due to our breach of contract, breach of fiduciary duty and falsifying documents*, among other things, to our clients, the managing members of Creative Werks LLC, governmental regulatory agencies, *the end users and society at large. (Emphasis added.)*

c. Other stakeholders could suffer injury, *illness or death*; in addition, others can suffer loss of employment and economic instability. (Emphasis added.)

d. Analysis of the current Food Safety Plans at Creative Werks LLC, evidences that Creative Werks LLC, *has year over year, consistently been out of regulatory compliance with the Federal Food, Drug, and Cosmetic Act "hereinafter"* (FD&C Act), as amended by the Food Safety Modernization Act "hereinafter" FSMA and its relevant subparts. (Emphasis added.)

e. Further analysis suggests that there is *no cognitive recognition* (Emphasis added.) *that the Food Safety Plans are out of legal compliance with FSMA.*

f. Also, it can be reasonably inferred that there is a high probability factor that our non-compliance is *a root cause in lost business opportunities*, such as Pepsi. (Emphasis added.)

g. Further, *there is no evidence that a formidable plan of action is in place or being developed to remediate the noncompliance* and outstanding compliance issues. (Emphasis added.)

h. Additionally, there has been *an improper interpretation, analysis and application of the relevant statutes*, standards and regulations relative to the business unit's objectives of manufacturing, co-packing and compliance. (Emphasis added.)

*i.* *Since the inception of the Preventive Controls regulations, Creative Werks LLC has never been compliant and has had repeated violations from numerous customer audits.* (Emphasis added.)

j. *Also, a culture that is diametrically opposed to the transparency mantra of Creative Werks LLC has evolved*. (Emphasis added.)

   *i.* Further, this culture exhibits and encourages a blatant *disregard for the law*. (Emphasis added.)

   ii. Additionally, this conduct is in *direct contravention to domestic and international regulatory framework used for transparency to promote and underscore food protection initiative*s. (Emphasis added.)

k. Failure to act swiftly within the prescribed timeframe will also subject us to *additional civil and criminal liabilities* for once again failing to comply with the standards. (Emphasis added.)

l. E.g. the incident raised, by the *FDA in its September 2022 inspection, relative to product failure in conjunction with Pepsi that was reported in October of 2021*. (Emphasis added.)

   i. This incident has an expiry date for civil liability of October 2023.

   ii. *Criminal liability has no statute of limitation*. (Emphasis added.)

m. **Recommendations:**

i. Implement an immediate course correction.

ii. *Refrain from hiring any persons or purchasing any compliance aids until a needs assessment is conducted* and analyzed that supports a formidable plan of action accompanied by a supporting business case. (Emphasis added.)

*iii. Implement proper oversight.* (Emphasis added.)

iv. *Identify, interpret and apply the proper relevant statutes, standards and regulations necessary to achieve compliance.* (Emphasis added.)

v. Line balance the appropriate standards against customer requirements.

vi. Develop, implement and sustain communication plans.

In response to the above and based on Dr. Knutson's review of the entire Report and numerous other Company records, Knutson concludes as follows:

1. The above statements cited from Complainant's [Report] are inflammatory, confusing, false, inaccurate, or misleading. Creative Werks provided numerous documents to me, and I reviewed 26 of the provided documents. The vast majority of the documents I reviewed were available to Ms. Madison at the time of her employment. I concluded that Creative Werks is a company with *very low-risk operations for the manufacture of packaging and filling of containers with food*. (Ex. A, par. 4) (Emphasis added.)

2. Ms. Madison uses inflammatory language to try to paint a picture of a company that is out of control and processing unsafe food. My review showed the *opposite*. (Emphasis added.) In fact, Creative Werks has extensive documentation; a well-staffed Quality department; has large, multi-national food manufacturers as customers; and complies with both state and federal regulations. I was pleased with the organized and plentiful documents covering much of food safety, and I found the representative documents well-written, concise, and clear…..The fact that the documents are written, revised, and signed is an excellent sign of compliance with the FDA rule. Creative Werks is a company with a full menu of documents and is not just getting by nor trying to cover up violations. (*Id*. at par. 5)

*3.* Ms. Madison's statement: While "*Creative Werks LLC's non-compliance with the relevant statutes, standards and regulations under FSMA is an inherent systematic and systemic issue throughout the organization that creates irreparable harms for all stakeholders*"…I reviewed two State of Illinois inspection reports (9, 10) and two FDA inspection reports (7, 8). Creative Werks passed all four inspections with no follow-up required. No follow-up to an FDA inspection is very rare, (emphasis

added.) yet alone two FDA inspections with no follow-up. *Both the State of Illinois and FDA believe Creative Werks to be in compliance.* (*Id*. at par. 6)

4. Ms. Madison makes the very serious allegation that documents were falsified due to non-compliance when she stated, "*More specifically for Creative Werks LLC, this non-compliance creates legal liability and culpability due to our breach of contract, breach of fiduciary duty and falsifying documents, among other things, to our clients, the managing members of Creative Werks LLC, governmental regulatory agencies, the end users and society at large."* I believe this allegation is ….personal opinion [not] a statement of fact. *My document review and the four government inspections show a company in compliance.* (Emphasis added.) (*Id*. at par. 7)

5. *Alleged Irreparable harm* from Ms. Madison's report consists of employees possibly losing limbs or scarring and chronic lifelong illness or death of consumers. These scenarios have been associated with the food industry in the past, *but there is not a significant risk for any of these harms at or from Creative Werks based on my document review*. (Emphasis added.) In her complaint, Ms. Madison raises the concern for production employees with harm from X-ray instruments, but the instruments are serviced annually, which follows industry best practice and does not affect food safety. This statement from her report is also unfounded based on my review, *Other stakeholders could suffer injury, illness or death; in addition, others can suffer loss of employment and economic instability. The food industry and employees working in Quality departments take the responsibility for the prevention of injury, illness, or death very seriously, and Creative Werks has the documents to prove this, starting with the hazard analysis found in each of the four (4) food safety plans that I reviewed. (Emphasis added.)* (*Id*. at par. 8)

6. I have struggled to understand Ms. Madison's perspective and have found <u>*no basis*</u> (emphasis added) in much of her discussion; for example, *Analysis of the current Food Safety Plans at Creative Werks LLC, evidences that Creative Werks LLC, has year over year, consistently been out of regulatory compliance with the Federal Food, Drug, and Cosmetic Act "…..* I reviewed four food safety plans (FSPs) from Creative Werks that were all available to Ms. Madison at the time of her employment, and <u>*all were in compliance*</u>. (Emphasis added). The FSP for Dunkaroos is attached to her report in Exhibit C and appears to have her comments entered in red to mark areas of non-compliance. (*Id*. at par. 9). The Expert Report further dives into Complainant's alleged deficiencies of the FSP, and found the asserted deficiencies to be <u>*wholly unfounded and incorrect.*</u> (Emphasis added.) See *Id*. at par. 9 (a-g).

Knutson further lays out that:

7. The Food Safety Plans are in compliance, so the following quotes from her report become <u>*null with no additional evidence*</u>. (Emphasis added)

a. *Further analysis suggests that there is no cognitive recognition that the Food Safety Plans are out of legal compliance with FSMA. [Reflecting Madison's false statement]*
b. *Additionally, there has been an improper interpretation, analysis and application of the relevant statutes, standards and regulations relative to the business unit's objectives of manufacturing, co-packing and compliance. [Reflecting Madison's false statement]*
c. *Since the inception of the Preventive Controls regulations, Creative Werks LLC has never been compliant and has had repeated violations from numerous customer audits.* Audits carry no force of law. *[Reflecting Madison's false statement]*
d. *Failure to act swiftly within the prescribed timeframe will also subject us to additional civil and criminal liabilities for once again failing to comply with the standards. [Reflecting Madison's false statement]*[1]

Knutson's Expert Report stands on its own and deftly notes dozens of instances reflecting statements in Madison's Report that contain: (a) misleading statements (pars. 12, 13, 48, 49); (b) gross misstatements of the law (par. 14 -16, 52); (c) objectively untrue statements contrary to written documentation relating to the FDA inspections that she refers to ((pars. 16 &17); (d) inappropriate and inflated conclusions and/or a false urgency (par. 15-16; 22); (e) confusing information and difficult to decipher (par. 21); (f) a failure to work in a team-like manner, generally inherent in this area of work (par. 28 & 29); (g) misrepresentations conflating customer audits with FDA, regulatory inspections (41); (h) gross misunderstandings of FSMA regarding the need to inspect customer-directed packing goods (par. 43); and (i) misrepresentations of Creative Werks' Food Safety Plans as not FSMA compliant. (Par. 37.)

Knutson's Expert Report further concludes that:

> The review of documents shows that [C]reative [W]erks appears to have the resources necessary to implement food safety policies and procedures…..Her short time at [C]reative [W]erks and lack of understanding of the law, complicated by overlapping customer requirements and quality issues with food safety caused her to make a crisis where there was no crisis. I find her actions unprofessional and unreasonable for her or anyone working in the food industry. (pg. 14)

[1] Also, while Madison refers to "*additional* civil criminal liabilities in her Report, Creative Werks has *never* been charged with or found liable for civil or criminal liabilities in the past.

Clearly, the totality of the Expert Report demonstrates what appears to be Madison's intentional effort to misstate and distort FDA-related documents and regulation to mislead Creative Werks' management. The Expert Report futher shows that Madison misinterpreted customer communications, reported wholly fictitious issues, failed to engage in adequate research to support her radical conclusions, and lacks accurate knowledge of the law and regulations relevant to her position as Quality Regulatory Manager, information that she purported to have known. Moreover, as the Expert Report notes, Madison's actions showed a complete lack of professionalism and a significant lack of critical skill sets required for her job.

In addition to the Report that led directly to her termination, Madison's Complaint is also riddled with unsupported conclusions/allegations and demonstrably false statements made to bolster her false allegations. The chart below reflects the Complaint's false statements and gross mischaracterizations, along with Zicher's response, supported by his declaration attached hereto as Exhibit C.

| **Madison's Complaint** | **Page** | **Zicher Response** |
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| On September 28, 2022, there was an FDA inspection "because of a consumer complaint." | 1 | This is a demonstrably false statement based on the face of the FDA Establishment Investigation Report ("EIR"). Rather, this was an initial and routine inspection and was not related to or the result of any consumer complaint. As stated in the EIR, the inspection was a routine examination and was the FDA's first examination of the facility. Madison was unable to complete her duties and attend the inspection because she was wearing clothing and accessories that violated basic safety protocol, including Good Manufacturing Policy ("GMP"). |
| The Company had "no knowledge of October 2021 Incident" where allegedly there was discoloring on | 1 | Prior to the inspection, Creative Werks had no knowledge of this October 2021 incident or consumer complaint. Creative Werks learned of the complaint during the inspection. |

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| the packaging for a Cheetos snack product from Frito Lay. | | Apparently, a customer reported lid discoloration (a non-safety issue) to the FDA, through the FDA's reporting system. The FDA had never provided notice of that consumer complaint prior to the inspection. Creative Werks subsequently contacted PepsiCo, Frito Lay's parent company and the manufacturer of the food product at issue, and confirmed that PepsiCo never received FDA notice of said consumer complaint. As such, Madison fabricated a lie about Creative Werks knowing about the alleged FDA Complaint. |
| Complainant alleged that the Company was aware "since May/June of 2021 that there were issues regarding this particular product" | 1 | This is also false. Madison is referring to a plastic tub package for puffed cheddar Cheeto's, a Frito Lay product (the "Snack"). Frito Lay received a consumer complaint in May/June 2021 through its *own* consumer complaint process (not from the FDA) indicating that a customer noticed a black substance around the tub cover where the cap connected to the tub. After consultation, Creative Werks and Frito Lay determined that the packaging cap could melt in the final sealing process, causing some black discoloration. Creative Werks subsequently corrected that issue. Moreover, Creative Werks had ceased packaging the Snack and had no plans of restarting the same. Accordingly, Madison misstated facts about this issue in the Complaint and was referring to an issue that was not even relevant at the time of her employment. |
| Madison alleged that "during FDA inspection, Mr. Zicher refused to provide any evidence of an investigation regarding the May/June [Cheeto packaging] complaint" | 1 | This is a demonstrably false statement. Firstly, the FDA investigation was not predicated upon any FDA complaint about the Snack's packaging, but rather was an initial, routine examination. During the investigation, the FDA inspector mentioned the single FDA consumer complaint. The Company notified the FDA inspector that it had never received notice of the FDA consumer complaint. Notwithstanding, to be fully transparent, Creative Werks informed the FDA inspector that it had previously learned about a packaging issue from its client, Frito Lay, and explained what measures it engaged in to resolve that issue with its client. Upon request of the FDA inspector, Creative Werks |

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| | | allowed and provided to the inspector an electronic document review, reflecting the remediation efforts taken. Those remediation efforts are even reflected in the EIR. Accordingly, Madison's assertion that the company refused to provide the relevant documents to the FDA is demonstrably false and is a reckless and libelous statement. |
| Complainant further asserted with respect to the initial FDA inspection, "I understand in hindsight, he refused because we did not likely have it, as evidenced by the lack of documentation and record keeping in compliance with FSMA" | 1 | This is a false statement. All relevant information was provided to the FDA inspector on-site regarding the Frito Lay consumer complaint. Creative Werks made the records relating to the same available, and the FDA inspector reviewed them on site. There were no records existing relating to the FDA consumer complaint because notice was never provided of the same. This is another instance of the Complaint containing false and misleading statements. |
| "During the FDA visit several observations were made that were communicated to us at the closure of the audit. Some of the items the FDA raised included improper record-keeping, sanitation, pest control and failure to timely remediate an outstanding compliance issues" | 1 to 2 | Complainant is referring to the EIR. She cites to the EIR's findings, but these were not material enough for the FDA to issue a Form 483 or anything further with respect to same. An FDA Form 483 is issued to firm management at the conclusion of an inspection if an investigator has observed any conditions that in their judgment may constitute violations of FSMA. Notwithstanding the FDA's decision to not issue a Form 483, Creative Werks held a meeting of all impacted departments and thereafter, made timely remediation efforts to solve for all of the noted issues in the EIR. |
| "Respondent did not have adequate food safety plans…for each and every item that it packaged or manufactured, as required by FDA regulation." | 2 | This is a false statement and reflects a material incorrect understanding of food safety plan regulations. Creative Werks, in fact, at all relevant times (including before and after Madison's employment) has had written food safety plans for each of its product categories and manufactured packages. The Company has four (4) food safety plans addressing (i) packaging food, (ii) creation of packages (e.g. blow molding plastic packages/tubes), (iii) coffee packaging products, and (iv) for the Dunkaroos project. Madison incorrectly argues that each SKU (or individual/marketable unit) |

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| | | required its own specific food safety plan. Such a requirement does not exist under any FSMA regulations or guidelines. |
| Madison asserted "It also underscored outstanding customer audit findings that had to be remediated and requests for compliance documentation from customers" | 2 | As addressed below, Madison materially mischaracterized and fabricated statements regarding customer generated audit findings and/or requests for compliance from customers. It is notable that the customer audit findings she broadly refers to did not relate to any food safety issues or defects impacting any consumer packaging. Moreover, the Company worked with its clients to address all matters raised in their audits—a regular process that occurred to maintain best practices and quality control. With respect to Madison's reference to the "requests for compliance documentation," this is also a gross misstatement of fact, as addressed below. |
| "Mr. Zicher instructed and confirmed that the [Food Safety Plan] that he drafted for Dunkaroos be used as a template or model FSP for everything at CW." | 2 | This is true, in part, but Creative Werks specifically hired and tasked Madison with updating the Food Safety Plans across all projects. However, the existing Food Safety Plans, then in place, were fully compliant and fully addressed all customer concerns and FDA requirements. The Dunkaroos Plan was the most recent and included greater detail than what most Creative Werks' customers required. The continuing goal, which contemplated Madison's efforts, was to continually update and improve all Food Safety Plans, to include greater detail. The Company's goal was and continues to be an ongoing effort to improve its Food Safety Plans each year. |
| Complainant was provided with a 2016 Food Safety Preventive Controls Alliance and Kraft Document | 2 | Madison met with Zicher to walk through the Food Safety Plan update project, spending considerable time discussing her expected efforts to update the Food Safety Plan formats and add new information. Both new and old Safety Plans were discussed at that time. Madison was provided information and training enabling her access to all prior and then current Food Safety Plans beyond the 2016 Plan Madison refers to. Her omission of the other Food Safety Plans that she knew about and had access to appears to be an attempt to |

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| | | mischaracterize the Company's actual compliance with FDA regulations. |
| "Each product needed its own FSP because they all have different ingredients, customer specifications, and other attributes that warrant and necessitate a customized FSP, in addition to other statutory requirements" | 2 | This is false and reflects a clear misunderstanding of FSMA regulation. The Company had a Food Safety Plan for each product category that it packed. FSMA does not require an individualized FSP for each SKU. |
| "Nestle had unresolved audit findings since July of 2022 directly tied to compliance failures…" | 2 | While true that Creative Werks was working with Nestle to resolve some documentation issues, Madison omits to report that Creative Werks was actively interacting with Nestle on a monthly basis and working to meet all requests, which continued to evolve. Madison had access to this information when she was employed and failed to make any inquiry with as to whether there were any unresolved issues with Nestle, material or otherwise.<br><br>Importantly too, Complainant's allegations also fail to address the materiality of the Nestle issues to which she refers, which were not safety issue nor quality problems with the packaging. Rather, she is merely referring to an ongoing and routine improvement program, that Nestle in particular, is very proactive with respect to its co-packers. |
| "There had been 139 outstanding document requests from customers dating back to 2021…" | 2 | This is a wholly false statement, arising from Madison's failure to adequately research this issue and would have been discovered by her as false as well if she had raised this issue with Zicher before publishing this false assertion in her work product provided to the President.<br><br>The Company uses an automated communication, or ERP system, with all of its customers called "Trace Gains" In 2021 one of its customers was divesting a portion of its confectionary portfolio and this transaction generated hundreds of automated requests for particular specifications for products. These automated requests were sent in error and requested specifications that were not intended |

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| | | to be nor relating to work to be performed by Creative Werks.<br><br>The Company had coordinated with the customer via email (not this automated system) to resolve this issue during this the customer transaction/transfer/divestment.<br><br>The 139 requests had not been removed yet from the automated system, but they were not outstanding issues to be addressed. One of the duties that Complainant was hired to do was to clean these requests out of the system.<br><br>This is another material mischaracterization in Report and the Complaint arising from Madison's failure to adequately research this issue. |
| "I also told him I was not comfortable providing false or misleading information. Specifically, telling clients everything is ok when it is not" | 2 | Claimant is wholly fabricating this allegation. Zicher's sworn declaration denies that such a conversation took place nor did Claimant otherwise report such a conversation with anyone else in the Food Safety/Regulatory Department. |
| "I was instructed to check boxes on forms to confirm that everything was vetted properly when it was not" | 2 to 3 | Claimant is wholly fabricating this allegation. Zicher's sworn declaration denies that such a conversation took place nor did Claimant otherwise report such a conversation with anyone else in the Food Safety/Regulatory Department. |
| "For instance, I was instructed to accept incoming material because it was coming from Mondelez and to disregard protocol." | 3 | This reflects another instance of Madison not understanding the applicable FSMA guidelines and yet another issue that she would have realized was incorrect had she gone through normal routes of communication with Zicher, her supervisor.<br><br>She refers to packaging product provided by a client, Mondelez. It is not a food product, but a packaging product (such as film or plastic) from Canada. FSMA allows co-packers to rely on their customer's vendor and supplier verifications, when the packaging product comes directly from the co-packer's customer. |

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| | | Also, in this instance, the Company did not require a Foreign Supplier Verification Program because the Company was not the importer, rather the client was the importer. |
| "Similar instances of blatantly disregarding protocol occurred, relative to notifying customers of an FDA visit and the reason for the visit." | 3 | This is a wholly fabricated and false statement. After the FDA inspection, key Creative Werks employees, including Madison, had a meeting to evaluate how to respond to the FDA inspection and how to remediate the issues noted. After receiving the EIR, it was considered whether to respond to the FDA and request edits or corrections to the EIR. While some of the findings were inaccurate, it was decided that no appeal would pursued.<br><br>Creative Werks notified all customers of the inspection via email, and they were told it was routine inspection.<br><br>This reflects another instance of Madison reporting false information to the CEO that she would have learned was incorrect had she gone through existing channels of communications with Zicher, her supervisor. |
| With respect to the Blue Diamond Audit, "Mr. Zicher instructed me to use whatever we had because nobody paid attention and they don't read them anyway." | 3 | Claimant is wholly fabricating this allegation. Zicher's sworn declaration denies that such a conversation took place nor did Claimant otherwise report such a conversation with anyone else in the Food Safety/Regulatory Department. |
| "On October 20, 2022, I drafted a risk analysis outlining some concerns I had regarding lack of FDA compliance." | 3 | Rather than complete and improve the Food Safety Plans that she was hired to update and improve, Madison wrote her 78-page Report, which she never provided to Zicher. |
| "I had attempted to discuss these issues with Mr. Zicher, but he was unresponsive." | 3 | Madison is wholly fabricating this allegation. Zicher's sworn declaration denies that such a conversation took place nor did Claimant otherwise report such a conversation with anyone else in the Food Safety/Regulatory Department.<br><br>Moreover, it would stand to reason that she would have provided a hard copy or emailed the work product at issue to Zicher, her supervisor if she actually attempted to discuss it with him. |

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| | | Zicher's sworn declaration shows that he first reviewed the Report on October 31, 2022, days after Madison's meeting with Creative Werks' President. |
| "Mr. Zicher admitted they knew as far back as May 2021 that they had products that were non-conforming. He was not able to demonstrate that any remediation was performed. Mr. Zicher further offered that this issue was no longer relevant, as CW was no longer doing business with Pepsi? | 3 to 4 | As noted above herein, Madison is referring to two (2) Different incidents. Moreover, these did not reflect any deficiencies in any Food Safety Plans. Madison's statement is correct only with respect to noting that the alleged non-conformance issue was no longer relevant because that packing project had long been terminated. |
| "I also reported that the FDA Inspector was asking for documents. Mr. Zicher pushed back and refused." | 4 | This is another example of a gross falsification of facts. The Company provided all documents requested by the FDA inspector, and walked the inspector through the electronic documents showing the relevant remediation efforts taken to resolve the Frito Lay Consumer Complaint. |
| X-Ray Machine | 4 | Inexplicable - the X Ray machine is used commonly in the industry and is generally recognized as safe. The Company follows the manufacturer's and any other applicable safety guidelines with respect to its X Ray machine. There have never been any injuries relating to same. Had Madison raised this issue with her Zicher, she would have been provided with the published safety recommendations and would have seen Creative Werks' compliance with the same. She did not do this before making her Report. |
| "Could not go into the manufacturing facility during the FDA inspection because I had on a dress, earrings and fingernails" | 5 | Complainant did not attend the FDA inspection, which occurred on her second day of work. Her clothing, jewelry, glasses (with rhinestones on the temple) and fingernails did not meet the standard, common in the industry to be present in the co-packing areas.<br><br>Madison was informed of these standards when she accepted the position, and anyone with her "experience" should have known this. Accordingly, her failure to follow well-known safety procedures prevented her from doing her job and participating in the referenced FDA inspection. This demonstrated a material lack of |

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| | | following well know procedures that prevented from doing her job. |
| The Company "declined to provide my personnel file" | 6 | This is a demonstrably false statement. Creative Werks provided Madison her personnel file upon request. |

Furthermore, the Department of Labor should scrutinize Madison's allegations especially closely. After Madison's termination, Creative Werks learned of her involvement in a federal civil case wherein she demonstrated an incredible lack of veracity and honesty and where she exhibited a willingness to mischaracterize matters to such a degree, the her character traits should be considered when the Complaint is reviewed. (*See Madison v. Kenco Logistic Services*, 2017 WL 4532248 *1 (C.D. Ill, Sept. 22, 2017). In 2017, Madison filed an action against her former employer (that was later dismissed in its entirety), and when filing the action in Federal District Court, she sought a waiver of a $400 filing fee asserting she had only $10.00 to her name. *Id*. Because of irregularities in her sworn statements, the Central District Court of Illinois held a hearing to test the accuracy and truthfulness of Madison's sworn statement of her financial condition. *Id*. The Court made extraordinary findings as to Madison's representations and her testimony:

(a) that her testimony during the hearing was "vague, elusive and completing lacked credibility (*Id*. at *2);

(b) that she failed to explain her ability to make her mortgage payments;

(c) that she failed to explain how she was able to pay for electricity, internet and cable bills that she was current on (*Id*.);

(d) that her testimony was "unbelievable" (*Id*. at *3);

(e) that she failed to admit she was receiving royalty checks for "$8,000 or $9,000" every couple of months (*Id*.);

(f) that she initially admitted to having received annuities from her mother's death declaring it to be "100 something" and under subsequent examination later admitted she "meant $100,000" (*Id*. at 4);

(g) found there to be glaring contradictions between her deposition statements and her sworn court petition (*Id*.);

(h) that she "had not been honest" (*Id*. at 7); and

(i) that she "lied" to the Illinois Department of Human Relations or the Court (*Id*. at 9).

The Central District dismissed her claim for "failure to be honest and forthright." (*Id*.)

**APPLICABLE LEGAL STANDARD**

Here, in order for Madison to prevail, she must provide, under a preponderance of the evidence standard, the following three elements: (1) that she engaged in "protected activity"; (2) that she suffered an adverse action; and (3) that the protected activity was a contributing factor in the adverse action. *See* 21 U.S.C. § 399(d)(b)(2)(C). A contributing factor is ''any factor which, alone or in connection with other factors, tends to affect in any way the outcome of the decision.'' *Marano v. Dep't of Justice*, 2 F.3d 1137, 1140 (Fed. Cir. 1993).[2]

[2] It is further the case that an employee engaged in relaying safety or regulatory issues to her employer, does not give said employee immunity from termination if in doing so they act in a provocative, intemperate, volatile or antagonistic behavior. *See e.g., Formella v. U.S. Dep't of Lab*., 628 F.3d 381, 387 (7th Cir. 2010) (employee reported safety issue on truck but his manner of reporting gave the employer cause for termination notwithstanding the underlying protective activity actions of employee). Indeed, the manner in which an employee engaged in protected activity "must be balanced against the employer's right to maintain order and respect." Id. (*citing NLRB v. Thor Power Tool Co.*, 351 F.2d 584, 587 (7th Cir.1965)); *see also Perez v. Union Pac. R.R. Co.*, No. 19 C 4135, 2023 WL 415543, at *6 (N.D. Ill. Jan. 24, 2023) (just because an

It is a recognized defense, if Creative Werks can demonstrate that it would have taken the same adverse action in the absence of the alleged protected activity. As such, even if the employee established the above four elements, the employer may avoid liability if it can prove that it "would have taken the same unfavorable personnel action in the absence of that [protected] behavior." *Harp v. Charter Commc'ns, Inc.*, 558 F.3d 722, 723 (7th Cir. 2009); *Riddle v. First Tenn. Bank, Nat. Ass'n*, 497 F. App'x 588, 596 (6th Cir. 2012).

Here, Madison did not meet the first element required for her to succeed on her claim because she was not engaged in a valid "protected activity" and Creative Werks can demonstrate that that it would have taken the same adverse action even if her actions were considered "protected activities."

**Lack of Protected Activity**

It is acknowledged that under FSMA, an entity engaged in the packaging of food may not retaliate against an employee because the employee provided to the employer information relating to any violation of, or any act or omission the employee "*reasonably believes*" to be a violation of any provision of FSMA. *See* 21 U.S.C. 399d(a)(1). To have a "reasonable belief" under FSMA, a complainant must have both a *subjective*, good faith belief and an *objectively* reasonable belief that the complained-of conduct constituted a violation of FSMA or another regulation or standard. *See Sylvester v. Parexel Int'l LLC*, ARB No. 07-123, 2011 WL 2165854, at * 11-12 (ARB May 25, 2011).

The requirement that the complainant have a subjective, good faith belief is satisfied only if the complainant "actually believed that the conduct complained of violated the relevant law."

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employee's termination includes a chain of events starting with protected activity, does not necessarily mean that was a contributing factor when taking all facts into account).

(*Id*.) When determining if a complainant has an objective "reasonable" belief of a violation, this standard is based on "the knowledge available to a reasonable person in *the same factual circumstances with the same training and experience as the aggrieved employee*.'' *Harp v. Charter Commc'ns*, 558 F.3d 722, 723 (7th Cir. 2009) (emphasis added); *see also Yuan Xie v. Hospira, Inc.*, No. 10 C 6777, 2011 WL 3921451, at *5 (N.D. Ill. Sept. 2, 2011) (if a complaint made with respect to an employer is not objectively reasonable, it is not "protected activity.")

Here, it is clear that Madison had neither a subjective, objective, nor reasonable belief in the alarmist, exaggerated and intentionally misleading Report that Madison now asserts was her protected activity. The subjective standard cannot be met if the employee at issue did not "reasonably" and "actually" believe" there to have been underlying FSMA violations. *See* 21 U.S.C. 399d(a)(1); *Harp*, 558 F.3d at 723; *Sylvester*, ARB No. 07-123, 2011 WL 2165854, at * 11-12.

As is well borne out and detailed in the Expert Report and Erich Zicher's Declaration, the Report is wholly predicated upon data and information that Madison clearly understood was not "actually" or "reasonably" believed by her. The face of the EIR directly contradicts her statements in the Report. She expressly purported to know and understand the relevant law, even attaching portions to her Report, but made false statements and conclusions about the same. With this all in mind, her alarmist conclusions were further not reasonably believed by her because she had access to underlying information, both in written form and available to her from Zicher (or the dozen or so other safety/regulatory employees) that would have contradicted her conclusions had she made any further investigation…something she certainly should have reasonably done before making rash and alarmist conclusions. She also did not see or report viewing any evidence whatsoever of any safety violations but stated in her report that there were serious risks of physical injury or

death. Certainly, Madison had her "reasons" for drafting the Report, but she had not met her burden of demonstrating that she had a subjective and reasonable belief in its contents.

Similarly, under the objective standard, it is clear that her alleged belief of FSMA violations were not objectively reasonably based on the knowledge available "to a reasonable person in *the same factual circumstances with the same training and experience"* as Complainant. Here, Complainant certainly has made a case for herself that she has significant work history having previously worked for an FDA/FSMA regulated entity and based on alleged extensive FDA/FSMA training in several higher educational institutions. Accordingly, she must be held to a *very high standard* when evaluating whether her beliefs expressed in the Report were *objectively* reasonable.

Here, the Report is clearly alarmist, exaggerated, and contains inaccurate, unsupported sweeping conclusions, all effectively asserting *in her own summary* that "Creative Werks LLC non-compliance to the relevant statutes, standards and regulations under the FSMA is an inherent and systematic issue throughout the organization that created irreparable harm for all stakeholders (*See* Report - Cover Page Abstract). However, as well borne out by Knutson, and Zicher's supplement, *no* reasonable person having Complainant's work experience and education could have "objectively" had a reasonable belief in the conclusions she reached with respect to the asserted lack of "inherent systematic" material non-compliance of FSMA regulations or dangerous conditions.

**Creative Werks Would Have Terminated Madison Even In the Absence of the Alleged Protective Activity.**

Fundamental to this particular set of circumstances at issue in this case, is the undisputable fact that Creative Werks hired Madison to assist with and improve its compliance with FSMA regulations. As such, as a starting place, it was certainly contemplated that part of Madison's job

duties would necessarily entail reviewing Creative Werks' FSMA compliance and report on issues that she felt were in need of improvement and/or any instances where she reasonably believed there to be operations that were short of FSMA regulatory standards. This is a company, moreover, who has long had staffing to conduct these same responsibilities, and a demonstrably rigorous system in place to understand, meet, and continually improve with respect to best practices and FSMA compliance.

Here, it is clear that Creative Werks had a legitimate basis to terminate Madison for her poor and misleading work product, notwithstanding Madison's attempt to insulate herself from termination by wrongfully asserting that she was terminated for bringing good faith safety issues to management—and asserting her termination was in retaliation for same. For example and greater context through analogy, if a safety engineer for a rocket company where to draft a safety report full of gross calculation errors that were not reasonable based upon the experience of the engineer in question, if said report was demonstrably based on fabricated evidence, if the report clearly utilized distorted test data, if the underlying issues reported upon were merely nominal non-safety related issues but the engineer then made broad unsupported catastrophic safety allegations, if the engineer omitted information in the report in an effort to present distorted conclusions, if the engineer failed to report and/or vet his "alleged" concerns with his supervisor (or other employees) in his safety/regulatory department in which he worked…it would be entirely understandable if said engineer was terminated. This hypothetical occurred here. Madison's Report was far outside of the bounds of work product for someone of her stated education and experience and, as a result, was problematic, showing that Creative Werks could not rely on her to complete certain core duties.

In this particular context, Creative Werks did *not* terminate Madison because she merely did her job and turned in a report reflecting opinions as to FSMA regulatory compliance shortcomings. Rather, Creative Werks terminated Madison because it was so clear that the Report was intentionally misleading, contained many examples of unsupported and wild conclusions, designed to mislead the Creative Werks, demonstrated a lack of integrity, demonstrated a lack of veracity, reflected a failure to fully investigate before reaching extraordinary conclusions, asserted irresponsible and unrealistic conclusions, created a work-product that was not well written for the educated and experienced audience it was intended for, was given to Creative Werks' President without first addressing with her own supervisor, and otherwise reflected a lack of ability to perform the tasks she was hired to do.

**Mitigation of Damages**

Finally, it should be clear from the above arguments, that Creative Werks has not violated the FSMA (i.e. it did not retaliate based on protected activity), but if and to the extent any liability were to be found (solely for purposes of argument) Madison had and has an obligation to mitigate her damages. In this respect, she has admitted to obtaining a new job only a few weeks after her termination wherein she is earning only $10,000 less per year although we are unaware of what other or new benefits she has that may be better than she had at Creative Werks. As such, if and to the extent any liability is found, further information will be required to confirm the nominal amount of asserted damages at issue.

**Creative Werks LLC**

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EXHIBIT A

creative werks


ABSTRACT

Creative Werks LLC's non-compliance to the relevant statutes, standards and regulations under FSMA is an inherent systematic and systemic issue throughout the organization that creates irreparable harms for all stakeholders.

Mary Madison
Quality Regulatory Manager

# REGULATORY BUSINESS PROBLEM

October 20, 2022

## Summary of Problem Statement

Creative Werks LLC's non-compliance with the relevant statutes, standards and regulations under FSMA is an inherent systematic and systemic issue throughout the organization that creates irreparable harms for all stakeholders. More specifically for Creative Werks LLC, this non-compliance creates legal liability and culpability due to our breach of contract, breach of fiduciary duty and falsifying documents, among other things, to our clients, the managing members of Creative Werks LLC, governmental regulatory agencies, the end users and society at large. Civil and criminal remedies are results of such liability and can be comprised of monetary judgements, fines, penalties, sanctions, suspension of operations and incarceration or a combination thereof. Other stakeholders could suffer injury, illness or death; in addition, others can suffer loss of employment and economic instability.

## Problem Statement

Analysis of the current Food Safety Plans at Creative Werks LLC., evidences that Creative Werks LLC., has year over year, consistently been out of regulatory compliance with the Federal Food, Drug, and Cosmetic Act "hereinafter" (FD&C Act), as amended by the Food Safety Modernization Act "hereinafter" FSMA and its relevant subparts.

Further analysis suggests that there is no cognitive recognition that the Food Safety Plans are out of legal compliance with FSMA. *(See Exhibit A)* Nor is it readily apparent that the lack of compliance is a causal connection to outstanding audit/compliance issues with current customers. *(See Exhibit B*) Also, it can be reasonably inferred that there is a high probability factor that our non-compliance is a root cause in lost business opportunities, such as Pepsi. Further, there is no evidence that a formidable plan of action is in place or being developed to remediate the noncompliance and outstanding compliance issues. *(Exhibit C)*

Moreover, analysis suggests that there has been a failure to apply the relevant statutes, standards and regulations. Additionally, there has been an improper interpretation, analysis and application of the relevant statutes, standards and regulations relative to the business unit's objectives of manufacturing, co-packing and compliance.

## Stakeholders

One hundred percent (100%) of our client, customer and vendor base is subject to the regulatory framework and guidance of the FD&C Act, as amended by FSMA.

One hundred percent (100%) of the end users are protected by the regulatory framework and guidance of the FD&C Act, as amended by FSMA.

One hundred percent (100%) of our organization is governed by the regulatory framework and guidance of the FD&C Act, as amended by FSMA.

## Compliance

Compliance is achieved by adherence to the relevant statutes, standards and regulations under FSMA and other regulatory schemes. Further, compliance is underscored by overlap and continuity of customer requirements and Creative Werks LLC's protocol's, procedures and policies; coupled, with robust communication and risk management plans skewed to the relevant statutes, standards and regulations under FSMA and other regulatory schemes.

Compliance is not achieved through buzzwords or the sole expressed use of Continuous Improvement methodologies and tools. Additionally, quality and compliance are often treated and used interchangeably; however, there is a vital difference between these two terms. Specifically, regulatory compliance is compulsory and must be followed by any business wishing to engage in the stream of commerce.

Non-compliance negatively affects our sustainability, goodwill, and profitability here at Creative Werks LLC. In addition, it creates a public health threat and potential public health crisis.

## Risks

A vast range of inherent risks exist that impacts our organization; such as, customer supplied/source suppliers to supplier/vendor performance matrices to allergen control among other risk factors. Risks can either be business or regulatory risks or a combination of both risks thereof. Each risk is to be evaluated cumulatively for maximum optimization, including internal risks. Further, there are risks associated with training, scientific validation and verification, monitoring, documentation, and recordkeeping that must be line balanced for verification of implementation and effectiveness, as required by law.

Ongoing risk management is essential in this ever-changing environment. This proactive stance helps protect our brand reputation and business while creating operational efficiencies. Failure to build mitigation strategies around business and compliance risks identified, forecloses opportunities to improve, avoid complacency and litigation.

## Cost of Doing Nothing

Since the inception of the Preventive Controls regulations, Creative Werks LLC has never been compliant and has had repeated violations from numerous customer audits. We also have approximately 139 open document requests from various customers that have been outstanding since 2021 that are inextricably linked to our non-compliance. *(See Exhibit D)* We also have lost business opportunities that translate into the loss of dollars, profitability and goodwill; translating into market share loss. Further, we have noted infractions and/or violations from the FDA for non-compliance that are available for public inspection and review.

Also, a culture that is diametrically opposed to the transparency mantra of Creative Werks LLC has evolved. Further, this culture exhibits and encourages a blatant disregard for the law. Additionally, this

conduct is in direct contravention to domestic and international regulatory framework used for transparency to promote and underscore food protection initiatives.

If we do nothing, we can expect more of these and other scenarios; along with an increase in lost revenue, increased legal exposure and lawsuits among other things.

Further if we do nothing, we will also be in violation of other subparts of FSMA that require us to act swiftly in implementing an immediate course correction among other things. Failure to act swiftly within the prescribed time frame will also subject us to additional civil and criminal liabilities for once again failing to comply with the standards.

## Legal Exposure

Legal liability is triggered each and every day that compliance is not achieved. It also occurs on a transactional level on multiple fronts for all stakeholders.

Legal liability is governed by statutes of limitations relative to the claims asserted that are tied to either state or federal laws.

For example, product liability has a two (2) year statute of limitation. The statute of limitation is triggered when the person becomes aware that they have been harmed.

E.g. the incident raised, by the FDA in its September 2022 inspection, relative to product failure in conjunction with Pepsi that was reported in October of 2021. This incident has an expiry date for civil liability of October 2023. Criminal liability has no statute of limitation.

Another example is our current production of Valentine and Easter products the legal exposure is two (2) years beyond an adverse event. i.e. after product distribution and consumption by the end user. This pushes this liability exposure out past Valentine and Easter of 2025.

Further, most recently legal precedent supports that insurance companies reject indemnifying insureds for breach of any fiduciary duty; including non-compliance; thus, leaving us to settle any outstanding judgments at law or debts with company assets.

## Recommendations:

Implement an immediate course correction.

Refrain from hiring any persons or purchasing any compliance aids until a needs assessment is conducted and analyzed that supports a formidable plan of action accompanied by a supporting business case.

Implement proper oversight.

Identify, interpret and apply the proper relevant statutes, standards and regulations necessary to achieve compliance.

Line balance the appropriate standards against customer requirements.

Develop, implement and sustain communication plans.

Implement a Risk Management program.

Contract Management

Choose a certification that synergizes all the necessary elements for compliance and success.

Answer questions as asked; speak only to issues at hand.

Refrain from comingling facts from various situations or instances.

Refrain from comingling relevant statutes, standards and regulations during audit and inspection proceedings.

**Other Recommendations:**

Restructure Creative Werks LLC to a series LLC to reduce liability and exposure. i.e. Have a series LLC for each client or venture. E.g. Creative Werks-PepsiCo LLC

# EXHIBIT A

# FSMA Final Rule for Preventive Controls for Human Food

*Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food*

- Federal Register Notice (https://www.federalregister.gov/articles/2015/09/17/2015-21920/current-good-manufacturing-practice-hazard-analysis-and-risk-based-preventive-controls-for-human)
- Docket Folder **FDA-2011-N-0920** (https://www.regulations.gov/docket/FDA-2011-N-0920) provides the full text of the Rule
- Questions & Answers (/food/food-safety-modernization-act-fsma/frequently-asked-questions-fsma#PC_Rules)
- Fact Sheet (/media/108775/download)

Generally, domestic and foreign food facilities that are required to register with section 415 of the Food, Drug, & Cosmetic Act must comply with the requirements for risk-based preventive controls mandated by the FDA Food Safety Modernization Act (FSMA) as well as the modernized Current Good Manufacturing Practices (CGMPs) of this rule (unless an exemption applies). It is important to note that applicability of the CGMPs is not dependent upon whether a facility is required to register.

This rule, which became final in September 2015, requires food facilities to have a food safety plan in place that includes an analysis of hazards and risk-based preventive controls to minimize or prevent the identified hazards.

Compliance dates are staggered, based on the size of the business, with separate dates for the requirements of the supply chain program. Training, education, and technical assistance are available for those covered by this rule.

### Upcoming Compliance Dates

**September 18, 2017:** Small businesses (businesses with fewer than 500 full-time equivalent employees)

**September 17, 2018:** Very small businesses (businesses averaging less than $1 million per year (adjusted for inflation) in annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale)

**September 17, 2018:** Facilities subject to the Pasteurized Milk Ordinance (for their Grade "A" milk and milk products; compliance date was extended to allow time for changes to the PMO to incorporate the requirements of this preventive controls rule)

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*All other businesses (also known as "large" businesses) were required to be in compliance on September 19, 2016.

* FDA will soon release a web page listing all FSMA compliance dates.

And the compliance dates for some facilities and activities have been extended. Check the extensions and clarifications page (/food/food-safety-modernization-act-fsma/compliance-date-extensions-and-clarifications-fsma-final-rules) for the most recent information.

See also Clarification of Compliance Date for Grade "A" Milk and Milk Products Covered by NCIMS under the PMO (https://www.federalregister.gov/documents/2015/11/18/2015-29340/current-good-manufacturing-practice-hazard-analysis-and-risk-based-preventive-controls-for-human) and What to Expect Now that the First Big FSMA Compliance Dates Are Here (/food/food-safety-modernization-act-fsma/what-expect-now-first-big-fsma-compliance-dates-are-here).

**Key Requirements**

## UPDATES TO THE CURRENT GOOD MANUFACTURING PRACTICES (CGMPs)

- Some provisions that used to be nonbinding, such as education and training, are now binding.
  - Management is required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties.
  - Such employees must have the necessary combination of education, training, and/or experience necessary to manufacture, process, pack, or hold food that is clean and safe. Individuals must receive training in the principles of food hygiene and food safety, including the importance of employee health and hygiene as appropriate to the food, the facility and the individual's assigned duties.
- The FDA's longstanding position that CGMPs address allergen cross-contact is now explicit in the regulatory text.
- CGMPs also now include a provision for holding and distribution of human food by-products that are used for animal food.

## FOOD SAFETY PLAN

In general, you are a covered facility if you are required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic (FD&C) Act. Covered facilities are required to have and implement a written food safety plan that includes:

- **Hazard analysis:** The first step is hazard identification, which must consider known or reasonably foreseeable biological, chemical, and physical hazards. These hazards could be present because they occur naturally, are unintentionally introduced, or are intentionally introduced for economic gain (if they affect the safety of the food).

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If the hazard analysis reveals one or more hazards that require a preventive control, the facility must have and implement written preventive controls for the identified hazards.

- **Preventive controls**: Facilities have the flexibility to tailor preventive controls to address hazards that occur in the products they manufacture. The preventive controls, which must be written, must be implemented to ensure that any hazards requiring a preventive control will be significantly minimized or prevented and help ensure that the food is not adulterated. The rule includes the following preventive controls:
    - **Process controls** include procedures that ensure the control parameters are met. Process controls can include operations such as cooking, refrigerating, and acidifying foods. They must include parameters and values (e.g., critical limits), as appropriate to the nature of the applicable control and its role in the facility's food safety system.
    - **Food allergen controls** are written procedures the facility must have and implement to control allergen cross-contact and ensure allergens are appropriately listed on the labels of packaged food products.
    - **Sanitation controls** are procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition to minimize or prevent hazards such as environmental pathogens, hazards from employees handling food, and food allergen hazards.
    - **Other Controls** are controls that are not described above but are necessary to ensure that a hazard requiring a preventive control will be significantly minimized or prevented.
- **Oversight and management of preventive controls:** Once a facility has identified a preventive control for a hazard, the facility must make sure that the controls are being met.
    - **Monitoring**: These procedures are designed to provide assurance that preventive controls are consistently performed. Monitoring is conducted as appropriate to the preventive control. For example, monitoring of a heat process to kill pathogens would include recording temperature values. Monitoring must be documented.
    - **Corrections**: These are steps taken, in a timely manner, to identify and correct a minor, isolated problem that occurs during food production.
    - **Corrective actions**: These include actions to identify and correct a problem implementing a preventive control, reduce the likelihood the problem will recur, evaluate affected food for safety, and prevent that food from entering commerce if you cannot ensure that the affected food is not adulterated. Corrective actions must be documented with records.
    - **Verification**: These activities are required to ensure that preventive controls are consistently implemented and effective in minimizing hazards. Examples of verification activities include scientifically validating process preventive controls to ensure that the control measure is capable of effectively controlling an identified hazard and calibrating (or checking the accuracy of) process monitoring and verification instruments such as thermometers. Verification activities also include reviewing records to ensure that monitoring and corrective actions (if necessary) are being conducted. Verification activities must be documented.

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Product testing and environmental monitoring are also possible verification activities, required as appropriate to the food, facility, nature of the preventive control, and the role of that control in the facility's food safety system. Environmental monitoring is required if the contamination of a ready-to-eat food with an environmental pathogen is a hazard the facility identified as requiring a preventive control.

- **Supply chain program:** Manufacturers must have and implement a risk-based supply chain program if the hazard analysis identifies a hazard that (1) requires a preventive control and (2) the control will be applied in the facility's supply chain.
    - Facilities do not need to have a supply-chain program if they control the hazard in their own facility, or if a subsequent entity (such as another processor) will control the hazard, and the facility follows applicable requirements.
    - Manufacturers are responsible for ensuring that raw materials and other ingredients requiring a supply-chain-applied control are received only from approved suppliers, or on a temporary basis from unapproved suppliers whose materials are subject to verification activities before being accepted for use. (Suppliers are approved by the facility after the facility considers several factors, such as a hazard analysis of the food, the entity that will be controlling that hazard, and supplier performance.)
    - Another entity in the supply chain, such as a broker or distributor, can conduct supplier verification activities, but the receiving facility must review and assess that entity's documentation that they verified the supplier's control of the hazard.
- **Recall plan:** If the hazard analysis identifies a hazard requiring a preventive control, the facility must have a written recall plan that describes the procedures to perform a recall of the product. The recall plan must include procedures to notify consignees, to notify the public when necessary, to conduct effectiveness checks and to appropriately dispose of recalled product.

**Assistance for Industry**

## GUIDANCES

FDA has developed guidance documents (listed in box at right) on subjects that include:

- Hazard analysis and preventive controls - Draft Guidance for Industry (/food/guidance-documents-regulatory-information-topic/draft-guidance-industry-hazard-analysis-and-risk-based-preventive-controls-human-food)
- Control of *Listeria monocytogenes* in Ready-To-Eat Foods - Draft Guidance for Industry (/food/guidance-documents-regulatory-information-topic/draft-guidance-industry-control-listeria-monocytogenes-ready-eat-foods)
- Small Entity Compliance Guide (/food/guidance-documents-regulatory-information-topic/guidance-industry-what-you-need-know-about-fda-regulation-current-good-manufacturing-practice-hazard) that explains the actions a small or very small business must take to comply with the rule.

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## TECHNICAL ASSISTANCE NETWORK

- The Technical Assistance Network (TAN) (/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan) is a central source of information for questions related to the FSMA rules, programs, and implementation strategies.
- Common FSMA TAN Questions (/about-fda/page-not-found)

## FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

- The Food Safety Preventive Controls Alliance (FSPCA) is a broad-based public private alliance consisting of key industry, academic, and government stakeholders whose mission is to support safe food production by developing a nationwide core curriculum, training, and outreach programs to assist companies producing human and animal food in complying with the preventive controls regulations. https://www.ifsh.iit.edu/fspca (https://www.ifsh.iit.edu/fspca) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- See FDA's FSMA Training Strategy (/food/food-safety-modernization-act-fsma/fsma-training) for more information on the Alliances and their role in helping industry understand the FSMA-based regulations.

## FOOD SAFETY PLAN BUILDER

The Food Safety Plan Builder (/food/food-safety-modernization-act-fsma/food-safety-plan-builder) (FSPB) is a free software application, developed by FDA, that businesses can download from the FDA's website to guide them, step-by-step, through the creation of a food safety plan, as required by FSMA.

- Download the Food Safety Plan Builder (https://www.accessdata.fda.gov/scripts/foodSafetyPlanBuilder/)
- View the training videos (https://www.youtube.com/playlist?list=PLey4Qe-Uxcxb9AGNwFj-oGlquHDZ-tkqo) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

## ADDITIONAL RESOURCES

- Food Safety Plan Builder (/food/food-safety-modernization-act-fsma/food-safety-plan-builder)
- FSMA Inflation Adjusted Cut Offs (/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs)
- What to Do if You're Covered by Both PC and FSVP Rules (/media/105388/download) (PDF: 304KB)
- Small Business Exemptions and Modified Requirements (/media/117785/download) (PDF: 128KB)
- FSMA Training (/food/food-safety-modernization-act-fsma/fsma-training)
- Qualified Facility Attestation (/qualified-facility-attestation)
- Supplier Evaluation Resources (https://datadashboard.fda.gov/ora/fd/fser.htm)
- Third-Party Audit Standards and FSMA Supplier Verification Requirements (/food/food-safety-modernization-act-fsma/industry-resources-third-party-audit-standards-and-fsma-supplier-

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verification-requirements)

- Accredited Third-Party Certification Program Voluntary Audit Templates (/food/importing-food-products-united-states/accredited-third-party-certification-program-voluntary-audit-templates)
- Food Safety Preventive Controls Alliance (/food/food-safety-modernization-act-fsma/food-safety-preventive-controls-alliance)

### Meetings and Webinars

- Webinar: Preventive Controls Hazard Analysis and Risk-Based Draft Guidance (/food/food-safety-modernization-act-fsma/fsma-webinar-preventive-controls-hazard-analysis-and-risk-based-draft-guidance)
- Preventive Controls for Human and Animal Food Final Rules Public Meeting (http://wayback.archive-it.org/7993/20170111073828/http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm461791.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) [ARCHIVED]
- Webinar Series (http://wayback.archive-it.org/7993/20170111073833/http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm461512.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) [ARCHIVED]

### Related Guidance

- Guidance for Industry: Current Good Manufacturing Practice and Preventive Controls, Foreign Supplier Verification Programs, Intentional Adulteration, and Produce Safety Regulations: Enforcement Policy Regarding Certain Provisions (/regulatory-information/search-fda-guidance-documents/guidance-industry-current-good-manufacturing-practice-and-preventive-controls-foreign-supplier)
- Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food (/food/guidance-documents-regulatory-information-topic/draft-guidance-industry-hazard-analysis-and-risk-based-preventive-controls-human-food)
- Guidance for Industry: Determination of Status as a Qualified Facility (/regulatory-information/search-fda-guidance-documents/guidance-industry-determination-status-qualified-facility)
- Guidance for Industry: Temporary Policy Regarding Preventive Controls and FSVP Food Supplier Verification Onsite Audit Requirements During the COVID-19 Public Health Emergency (/regulatory-information/search-fda-guidance-documents/temporary-policy-regarding-preventive-controls-and-fsvp-food-supplier-verification-onsite-audit)
- Guidance for Industry: Determining the Number of Employees for Purposes of the "Small Business" Definition in Parts 117 and 507 (/regulatory-information/search-fda-guidance-

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documents/guidance-industry-determining-number-employees-purposes-small-business-definition-parts-117-and-507)

- Draft Guidance for Industry: Guide to Minimize Food Safety Hazards of Fresh-cut Produce (/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-guide-minimize-food-safety-hazards-fresh-cut-produce)
- Guidance for Industry: Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food (/food/guidance-documents-regulatory-information-topic/guidance-industry-supply-chain-program-requirements-and-co-manufacturer-supplier-approval-and)
- Draft Guidance for Industry: Application of the "Solely Engaged" Exemptions in Parts 117 and 507 (/food/guidance-documents-regulatory-information-topic/draft-guidance-industry-application-solely-engaged-exemptions-parts-117-and-507)
- Guidance for Industry: What You Need to Know About the FDA Regulation: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Small Entity Compliance Guide (/food/guidance-documents-regulatory-information-topic/guidance-industry-what-you-need-know-about-fda-regulation-current-good-manufacturing-practice-hazard)
- Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA (/food/guidance-documents-regulatory-information-topic/draft-guidance-industry-describing-hazard-needs-control-documents-accompanying-food-required-four)
- Draft Guidance for Industry: Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities (/food/guidance-documents-regulatory-information-topic/draft-guidance-industry-classification-activities-harvesting-packing-holding-or)
- Guidance for Industry: Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs (/food/guidance-documents-regulatory-information-topic/guidance-industry-policy-regarding-certain-entities-subject-current-good-manufacturing-practice-and)

## Supporting Material

- Regulatory Impact Analysis (/about-fda/economic-impact-analyses-fda-regulations/summary-fsma-final-rulemaking-current-good-manufacturing-practice-and-hazard-analysis-and-risk-based)
- Qualitative Risk Assessment:Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm (PDF: 651KB) (/media/93523/download)
- Qualitative Risk Assessment: Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm: Response to Public Comments (PDF: 110KB) (/media/93531/download)

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## Additional Information

- Background on FSMA (/food/food-safety-modernization-act-fsma/background-fda-food-safety-modernization-act-fsma)
- 5 Steps Toward Working with FDA on Human and Animal Food Guidance Documents (/food/food-safety-modernization-act-fsma/working-fda-human-and-animal-food-guidance-documents)
- Case Study: Food Safety Guidelines for Cantaloupes (/food/food-safety-modernization-act-fsma/case-study-food-safety-guidelines-cantaloupes)
- Constituent Update - FDA Continues Enforcement Discretion Policy Relevant to Certain Co-Manufacturers under FSMA (/food/cfsan-constituent-updates/fda-continues-enforcement-discretion-policy-relevant-certain-co-manufacturers-under-fsma) (November 2019)

## Contact Us

- How to Contact FDA about FSMA (/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan)(Technical Assistance Network)

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# EXHIBIT B

NESTLE

| SECTION | REQUIREMENT | AUDITOR FINDINGS | RATING | AUDITOR NOTES | CAR # | CORRECTIVE ACTIONS | PERSON RESPONSIBLE | ESTIMATED DATE (See Comment) | STATUS | CODE |
|---|---|---|---|---|---|---|---|---|---|---|
| HACCP | All Nestlé products and their components, including raw materials, packaging materials and process aids, are considered in a HACCP study. All processing steps and movement are considered in the HACCP study. | The Ingredient Risk Assessment document lists potential hazards for high-level ingredient/WIP groups (e.g. chocolate with inclusions, chocolate, or nuts) however no risk assessment (evaluating severity / likelihood) is performed. Risk Assessment documented conclusion (See Auditor Notes) does not negate the site's responsibility to evaluate the risks of the site's incoming materials.<br><br>The current grouping of ingredients will not adequately support a proper risk assessment of incoming materials<br><br>Same finding for packaging and process. | Major | One Food Safety Plan for packaging (across all three factories), one for coffee, one for Tubes and Toppers<br><br>Documented conclusion reached on ingredient hazards in the Ingredient Risk Assessment states, "Client... have instituted policies around Biological and Chemical concerns with their food manufacturers which we verify through our Auto hold / CofA process" | 1 | Food safety plans will be re-written to included severity and likelihood.<br>Food safety plans will be re-drafted to include the hazard analysis within - not as a separate document. Packaging and process will also be included. | Angie | 1-Nov-22 | | |
| HACCP | An annual review of the HACCP study must take place and all updates must be captured. | Ingredient Risk Assessment changes are not included in the annual reviewed and no change control associated | Major | 11/4/21 Pkg Food Safety Plan | 2 | Since the risk assessment will be embedded within the food safety plan, it will become part of the annual review. New change control froms will include a review of the food safety plan for new processes or products. | Angie | 1-Nov-22 | | |
| Microbiology | The relevant pathogen(s) as well as the associated hygiene indicator(s) has been identified. | Relevant hygiene indicators are not be being tested (e.g. Eb for Salmonella) | Minor | Target organisms are Listeria spp and Salmonella; Currently uses hygiene indicators only to show effectiveness of cleaning (validations) | 3 | Will review the program and how best to address | Erich | 1-Oct-22 | | |

Preventive Control

Take screen shots if not working

Mandatory Documents
- Quality DOC
- forms
- Audit

Chapter 1-4

Chapter 5.
Unique → Criteria

A central form
Cert of documentation

Archive - Stuff

MAD
Major Allergy